SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

B.1 BACKGROUND/OBJECTIVES

A. BACKGROUND

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by, among other things, adding a new chapter granting the Food and Drug Administration (FDA) authority to regulate the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors. The Tobacco Control Act also amended the Comprehensive Smokeless Tobacco Health Education Act of 1986 (CSTHEA) to grant FDA authority to regulate certain health warnings that must appear on smokeless tobacco products.

The Contractor shall assist FDA in implementing the provisions of the FD&C Act, as amended by the Tobacco Control Act and other applicable statutory and regulatory provisions applicable to retailers during the term of this contract and any extensions thereto.

B. OBJECTIVES

The purpose of this work is to:

1. Facilitate the enforcement of the provisions cited in Section C with respect to tobacco retailers.
2. Conduct inspections of retailers that sell and advertise regulated tobacco products to determine compliance with the provisions cited in Section C and submit inspection results to FDA.
3. Collect, document, and preserve evidence of inspections and investigations.
4. Support FDA in any enforcement or judicial actions, including coordinating the drafting and execution of declarations by the Inspectors and narrative reports by the Inspectors and Minors who participated in inspections, arranging for their testimony if necessary, and furnishing evidence.
5. Respond to inquiries by FDA concerning inspections, data, and other information associated with this program.

The Contractor shall assist FDA in implementing the provisions of the FD&C Act, as amended by the Tobacco Control Act, and other applicable statutory and regulatory provisions applicable to retailers during the term of this Contract and any extensions thereto.

C. APPLICABLE LAWS AND REGULATIONS

REGULATIONS RESTRICTING THE SALE AND DISTRIBUTION OF CIGARETTES AND SMOKELESS TOBACCO TO PROTECT CHILDREN AND ADOLESCENTS

The Tobacco Control Act required FDA to reissue the 1996 final rule, "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and

Adolescents." The FDA has reissued this rule, which is codified at 21 Code of Federal Regulations (CFR) Part 1140. The Contractor shall conduct tobacco inspections for compliance with certain provisions of these regulations with respect to retail outlets on behalf of FDA. For illustration purposes, some, not all, of the provisions in 21 CFR Part 1140 that are subject to inspection by the Contractor under this Contract include:

- **Age and Photo Identification Restrictions – Retailers:**
  - May not sell regulated tobacco products to anyone younger than 18 years of age;
  - Must verify that any person under age 27 purchasing regulated tobacco products is at least 18 years old or older by means of photo identification containing the bearer's date of birth.

- **Advertising and Labeling Restrictions – Retailers:**
  - May not sell regulated tobacco products using vending machines (except in facilities where the retailer ensures no person younger than 18 is permitted to enter);
  - May not sell cigarettes, cigarette tobacco, or smokeless tobacco using self-service displays (except in facilities where the retailer ensures no person younger than 18 is permitted to enter);
  - May not break open cigarette or smokeless tobacco packages to sell products in smaller amounts such as single cigarettes (also called "loosies");
  - May not sell cigarette packages containing fewer than 20 cigarettes;
  - May not distribute or cause to be distributed free samples of regulated tobacco products, except for samples of smokeless tobacco products in the limited circumstances defined by the regulations;
  - May not sell flavored cigarettes.

SYNAR REGULATION

In addition to the Tobacco Control Act, the Department of Health and Human Services works to limit youth access to tobacco through the Synar Regulation. The Synar Regulation, which is administered by the Substance Abuse and Mental Health Services Administration's Center for Substance Abuse Prevention (SAMHSA/CSAP), requires the 50 states, the District of Columbia and 8 U.S. territories (American Samoa, Guam, Palau, Federated States of Micronesia, U.S. Virgin Islands, Puerto Rico, Marshall Islands and Commonwealth of the Northern Mariana Islands) to:

- Have in effect a law prohibiting any manufacturer, retailer, or distributor of tobacco products from selling or distributing such products to any individual younger than age 18;
- Enforce this law;
- Conduct annual, unannounced inspections (referred to as the Synar survey) in a way that provides a valid probability sample of tobacco sales outlets accessible to minors;
- Negotiate interim targets and a date to achieve a noncompliance rate (or retailer violation rate) of no more than 20 percent (SAMHSA required that each state reduce its retailer violation rate (RVR) to 20 percent or less by FY 2003); and
- Submit an annual report detailing state activities to enforce its law.

The annual Synar survey is separate from the FDA inspections under this Contract.

B.2 CONTRACT PRICE

The Contractor shall provide the services described in Section C, Description, Specifications, Work Statement. Except as otherwise specified in the Contract, the Contractor shall furnish the necessary personnel, materials, services, facilities, and otherwise do all things necessary for, or incident to, the performance of the work set forth herein. The Contractor shall be reimbursed for allowable, allocable, and reasonable costs for performance of these services.

The Contractor shall be paid on a cost-reimbursement basis for work completed. The cost is subject to the provisions of the Limitation of Cost, and the Allowable Cost and Payment clauses in Section I, Contract Clauses. Any required non-inspection travel will be reimbursed in accordance with the Federal Travel Regulations.

Base Period

(a) The estimated cost to the Government for performance of the contract under the Base Period of this contract, including direct and indirect costs is:

Period of Performance	Estimated Total Cost
Base Period	$

(b) Total funds currently available for payment and allotted to this contract are _____. The Contracting Officer (CO) may unilaterally allot additional funds to the contract.

(c) When the contract is fully funded, the provisions of Clause 52.232-20 "Limitations of Cost" and Clause 52.216-7 (ALTIII) "Allowable Cost and Payment" shall apply.

(d) It is estimated that the amount currently allotted will cover performance under the contract through [insert at time of award].

B.3 CONTRACT PRICE - OPTIONS

Option Period I – (dates shall be inserted at award)-12 months

The estimated cost to the Government for performance of the contract under Option Period I of this contract, including direct and indirect costs is _____.

Option Period II – (dates shall be inserted at award)- 12 months

The estimated cost for the contract for the Option Period II including direct and indirect costs is _____.

B.4 TRAVEL AND OTHER DIRECT COSTS

Any non-inspection related domestic travel incurred directly and specifically in the performance of this Contract, claimed by the Contractor, and accepted by the Contracting Officer shall be reimbursed as described below.

Domestic non-inspection related travel expenses incurred by the Contractor in direct performance of the Contract shall be paid provided such travel is necessary for the performance of this Contract and the cost does not exceed:

1. The lowest customary standard, coach, or equivalent airfare offered during normal business hours for air travel except when such accommodations: 1) require circuitous routing, 2) require travel during unreasonable hours, 3) excessively prolong travel, 4) result in increased costs that would offset transportation savings, 5) are not reasonably adequate for the physical or medical needs of the traveler, or 6) are not reasonably available to meet mission requirements. In order for costs in excess of customary standard or coach airfare to be considered allowable, the applicable exception must be documented and justified.
2. Costs of rail travel by most direct route, coach-class accommodations.
3. The prevailing mileage rate set forth in the Federal Travel Regulation (FTR) or reasonable actual expenses for travel by motor vehicle in effect on date of travel. Travel by motor vehicle, including rented automobile, shall be reimbursed on a reasonable actual expense basis, or at the Contractor's option, on a mileage basis at the prevailing FTR rate, plus any toll or ferry charges.
4. The prevailing rates set forth in the FTR for lodging, meals and incidental expenses.

Travel claims shall be submitted and included with the monthly invoices for approval.

B.5 Other Direct Costs

Notwithstanding Clause 52.216-7, Allowable Cost and Payment, and Clause 52.244-2, Subcontracts, of the Federal Acquisition Regulation (FAR), unless otherwise expressly provided elsewhere in the Contract or in any modification thereto, the cost of the following items or activities shall be unallowable as direct costs:
Acquisition by purchase or lease of any interest in real property;
Special rearrangement or alteration of facilities;
Purchase, lease, or rental of any item of general purpose such as office furniture or office equipment (including data tapes);
Travel to foreign countries; and
Food and beverage costs unless part of per diem expenses paid in accordance with the Federal Travel Regulations.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

C.1 SCOPE OF WORK

Independently and not as an agent of the Government, the Contractor shall furnish the necessary personnel, materials, services, equipment, facilities, and otherwise do all things necessary for the performance of the work described below. The Contractor may be required to coordinate the work under this Contract with other tobacco enforcement activities. Attachment 1 contains a list of materials necessary for conducting FDA tobacco compliance check inspections.

FDA is seeking inspection services in the jurisdictions listed in the table below. The approximate number and types of inspections required to be conducted for the base period and each option year for each jurisdiction are listed below. Inspection amounts shall be the same in the base period, option year 1, and option year 2. The FDA will consider alternatives to the numbers listed below, if provided with sufficient justification for how the jurisdiction reached the alternative number and how the jurisdiction will be able to complete the inspections proposed. However, at a minimum, the Contractor should complete inspections at 20% of the tobacco retail establishments, unless noted in the values below, and the Contractor shall not complete more than 1 contractor-directed inspection, as discussed in section C.1.5, per establishment. The numbers of retailers listed in the chart are estimates only and the actual number of inspections to be performed may differ as costs are incurred. The actual number of retailers in each Jurisdiction may vary.

	Contractor Directed Under Cover Buy (UB) Inspections	FDA-Directed UB Inspections	FDA-Directed Advertising & Labeling (AL) Inspections	Estimated number of tobacco retail establishments in jurisdiction
Alabama	3000	1000	1000	6948
American Samoa	200	100	100	210
Arizona	1000	500	500	4397
Arkansas	3600	400	400	4070
California	6000	1000	1000	41717
Colorado	3500	1500	1500	5219
Connecticut	3750	1000	1000	4146
Hawaii	350	100	100	1227
Illinois	4750	800	800	11619
Iowa	2600	200	200	3468
Kansas	2000	300	300	2838
Kentucky	4400	450	450	4986
Maine	1800	300	300	1890
Maryland	3000	550	550	5915
Massachusetts	6100	1000	1000	6826
Michigan	4800	1500	1500	9224
Minnesota	4500	900	900	4548
Mississippi	4000	500	500	9224
Missouri	4500	450	450	6097
New Hampshire	500	200	200	1420
New Jersey	6300	700	700	11716
Commonwealth of Northern Mariana Islands	200	100	100	211
Oklahoma	1200	500	500	4963
Pennsylvania	6000	1000	1000	17647
Rhode Island	1100	150	150	1130
Texas	6000	750	750	34868
Washington	3500	750	750	5709
West Virginia	1200	500	500	2433
Wisconsin	2750	600	600	7705

TECHNICAL REQUIREMENTS

C.1.1 TOBACCO RETAIL COMPLIANCE CHECK INSPECTION PROGRAM RESPONSIBILITIES

A. Contractor/Subcontractor

The Contractor shall be an agency or subdivision of a state or territory with the authority to conduct retail tobacco compliance check inspections. Examples of appropriate agencies may include: public health departments, food agencies, or drug agencies.

Any subcontractor must act as an agent for the Prime Contractor and employees of the subcontractor serving as inspectors will be required to undergo the commissioning process described below.

B. Program Coordinator/Backup Program Coordinator

The Contractor shall designate a Program Coordinator who shall be responsible for overall coordination, gathering information and evidence, and communicating with FDA. The Program Coordinator shall be responsible for all aspects of the program management work described herein. This position should be the main point of contact for FDA. The Contractor shall also designate a backup/alternate Program Coordinator so the Government will always have a point of contact. In the event that the PC and BPC are not available, the Contractor shall designate and notify the COR of a point of contact with authority to make decisions on behalf of the PC/BPC. The Program Coordinator shall be available at all times within the 40 hour work week to communicate with the FDA.

C. Inspectors

The Contractor shall conduct compliance check inspections through any health, food, or drug officer/employee of any State, Territory, or political subdivision thereof. These individuals must be United States citizens and be able to be commissioned as officers of the United States Department of Health and Human Services (HHS), Food and Drug Administration, under the authority of the FD&C Act.

Due to logistics and associated expenses, FDA recommends, to the extent practicable, the use of no more than thirty (30) Inspectors. If logistically possible, FDA prefers a majority of the Inspectors conducting the FDA compliance check inspections be dedicated on a full-time basis.

If the Contractor utilizes part-time Inspectors, those inspectors must maintain regular performance of inspections in order to remain active on this contract. Inspectors that do not perform a minimum of 10 inspections per month may be deactivated from the program.

The Contractor shall inform all Inspectors that they may be needed to testify as witnesses in administrative hearings during the period of performance of the contract. The Program Coordinator will maintain current contact information on all Inspectors who leave the program and this information shall be turned over to the Government at the end of the contract period.

The Program Coordinator will annually confirm the contact information for Inspectors who have left the program.

The Contractor shall maintain current contact information for all inspectors and minors currently employed by the Contractor. The contractor shall provide FDA with contact information as needed by FDA. The Contractor shall annually verify current contact information for all inspectors and minors who were employed within the past five years but are no longer employed by the Contractor, and the most recent contact information for such inspectors and minors shall be provided to FDA. Additionally FDA may request individual contact information that shall be provided within 5 days of the request.

D. Background Investigations/Commissioning Process

Prior to carrying out compliance check inspection activities, all Inspectors must be commissioned by FDA. All other employees under this contract, or under any subcontract, including the Program Coordinators, Backup Program Coordinators, Chaperones (staff dedicated to overseeing the safety of the Minors), administrative personnel, and supervisors will be subject to a background investigation and will be required to sign a Commitment to Protect Non-Public Information Agreement. Minors will not be commissioned and will not undergo a background investigation by FDA.

In general, the commissioning process begins with a background investigation, including a fingerprint check, credit check, and childcare check facilitated by FDA. Several parties within HHS may be involved in the process, with oversight by the Center for Tobacco Products (CTP). Any of these parties may contact the Contractor for additional information to facilitate the process. Upon clearance of the fingerprint check, a person may be commissioned while the background investigation continues.

The Contractor shall submit contact information for the person(s) or entity most familiar with their organization's background investigation procedure (if any) as well as that of the Subcontractor(s). FDA's Office of Security Operations (OSO) will discuss the Contractor's or Subcontractor's background clearance requirements with the respective security contact to assess whether the entity's existing background investigation is equivalent to the FDA's requirement which is a Federal Level 5 Minimum Background Investigation (MBI), Public Trust Background Investigation. Additionally, OSO will evaluate the clearances currently held by each individual required to have a background check under the Contract. If OSO determines that any additional element or information is needed to complete the required clearances, OSO will facilitate this process.

Within three weeks of being awarded the contract the Contractor shall provide the information for the available employees and Subcontractors to be commissioned/receive background investigations, and subsequently, immediately upon identifying new staff it wishes to have commissioned. More specifically, the Contractor shall provide FDA with each such person's name, work address, work phone number or cell phone number, and email address. The Contractor shall notify FDA if any of the employee information above changes.

Receiving a commission signifies that the employee has accepted a position of public trust and must comply with all applicable federal laws and ethical standards. Each FDA commission is issued for a period of five years. Employees and/or Subcontractors are responsible for

immediately notifying their Program Coordinator of any event or occurrence that could affect or change their status.

The issuance of a commission is discretionary, and FDA may revoke a commission at any time. Reasons for revocation may include, but are not limited to:

- The abuse or misuse of the commission;
- The transmittal of confidential information from a commissioned officer to individuals who are not employees or commissioned officers of HHS;
- A conflict of interest;
- Change in criminal or credit history;
- Substance abuse; or
- Behavior that may discredit FDA.

Upon separation of a commissioned employee or subcontractor employee, the Contractor shall ensure the commissioning credentials and/or certificates and all equipment are returned to the FDA as instructed by the COR.

E. Information Regarding Minors

Minors are an integral part of conducting compliance check inspections. The Contractor shall acquire Minors age 16 or 17 to participate in the program.

The Contractor shall keep at least one photo on file of each Minor involved in the Program. In order to document the Minors' appearance, the Contractor may determine that they should be photographed with frequent regularity and/or prior to conducting any undercover buy assignments. FDA protocol does not require Minors to carry photo identification for the undercover buy assignments. However, the Contractor may determine that Minors should carry valid photo identification and present identification if requested. Such decisions are left to the discretion of the Contractor. The Contractor must ensure that all minors follow the chosen protocol consistently.

The Contractor, rather than FDA, has the oversight responsibility for Minors involved in the Program. The Contractor shall ensure that the Minors are within the required age range by obtaining a copy of their birth certificates and or other government-issued identification and an original parental/legal guardian consent form. The Contractor shall obtain written permission from the Minor's parents/legal guardian and school, unless home schooled or otherwise not enrolled, if the Minor is going to conduct undercover buy assignments during school hours.

Identities of Minors are to remain as confidential as possible. However, in the event of possible enforcement or judicial action, the Minor's identity may be revealed and the Minor may need to provide a declaration and/or give oral testimony in a hearing. The Contractor must inform the Minors that they may be needed to testify as witnesses in administrative hearings during the period of performance of the contract. This information must be contained in the parental/legal guardian consent form. The Program Coordinator shall maintain current contact information on all Minors who leave the program and this information shall be turned over to the Government at

the end of the contract period. The Program Coordinator will annually confirm the contact information for Minors who have left the program.

All participating Minors shall have a Medical Release signed by a parent or legal guardian authorizing emergency medical treatment if necessary while under the supervision of a commissioned officer or chaperone. Supervising adults shall have an original of the Medical Release in the field whenever a minor is participating in inspections or training.

The Contractor shall secure a grant of immunity from the proper authorities prior to using Minors in any jurisdiction where it would be illegal to use Minors to conduct undercover buy assignments or where a minor's possession of tobacco products is illegal. The Contractor shall provide written proof of such immunity to FDA. FDA will determine adequacy prior to contractor conducting inspections in any jurisdiction.

The Contractor shall ensure that all Minors are insured against accidents or other injuries. If the Minors are not covered under the Contractor's current policy, the Contractor shall purchase the necessary insurance. The Contractor shall not conduct inspections until such insurance is secured for Minors. Proof of insurance, including automobile liability coverage for commissioned officers and chaperones transporting Minors, shall be maintained by the Contractor and made available to FDA upon request.

The Contractor shall input each Minor's unique identification number into FDA's Tobacco Inspection Management System (TIMS) once the Contractor receives access. The Minor's unique identification number shall be generated by the Contractor to protect the confidentiality of the Minor. The Contractor shall maintain information cross-referencing each unique identification number to a specific minor.

F. Conflicts of Interest

The Program Coordinator and individuals conducting compliance check inspections or responsible for compliance information or evidence are considered "covered persons" who shall not have significant financial interests in "covered companies." Covered companies include: (1) any company that the covered person inspects; (2) any company whose compliance information and/or evidence the covered person is responsible for gathering, maintaining, or reporting; or (3) any manufacturer, distributor, or importer of tobacco products.

Examples of significant financial interests include:

- The covered person or a close family member owns stock in a covered company, other than through ownership of shares of a mutual fund that invests in a covered company.
- The covered person or a close family member serves as an employee, trustee, officer, or director of a covered company.

In addition, a covered person shall not participate personally or substantially in any matter under the Contract that may significantly affect that person's own financial interests or the financial interests of:

- His or her spouse or minor child;
- An organization in which he or she serves as an officer, director, trustee, general partner or employee;
- His or her general partner; or

- A person with whom he or she is negotiating for or has an arrangement concerning prospective employment.

Upon discovery of a possible conflict of interest involving an employee or a subcontractor's employee, the jurisdiction must immediately notify FDA of the possible conflict of interest. The jurisdiction must investigate all possible conflicts of interest and provide findings to the COR within 90 days of learning of the possible conflict of interest.

These requirements are contractual, and do not alter, modify, or replace obligations imposed on the Program Coordinators or Commissioned Officers by any applicable federal law or ethical standard.

C.1.2 PROGRAM MANAGEMENT TASKS

The Contractor shall conduct all program management tasks through its Program Coordinator and Backup Program Coordinator or designated administrative personnel. These tasks include, but are not limited to, the following areas as described in detail elsewhere in the statement of work:

- Serving as the primary point of contact with FDA;
- Ensuring that personnel use FDA issued equipment to maintain program files, communicate with FDA, and manage the FDA program;
- Facilitating background checks and the commissioning process, and securing signed FDA Form 3398's for all Contractor employees;
- Securing and maintaining all required information and documents regarding minors;
- Ensuring no contract personnel has conflicts of interest;
- Attending initial, refresher, and in-person trainings;
- Providing training to inspectors and minors, and maintaining training records;
- Adding retailers to and editing existing retailer data in the Tobacco Inspection Management System (TIMS) to maintain an up-to-date list;
- Selecting retailers for inspection and creating inspection assignments;
- Reviewing inspection results, storing and maintaining chain of custody of evidence, and otherwise facilitating inspections;
- Assisting FDA with post-inspection follow-up, if required;
- Implementing, maintaining, and performing all work necessary under the quality control plan;
- Creating and submitting monthly reports and invoices;
- Securing former inspectors as experts where necessary; and
- Performing all other non-inspection functions that are necessary to ensure the program is able to obtain or maintain capacity to conduct inspections.

C.1.2. TOBACCO RETAIL INSPECTION PROGRAM TRAINING

1. Training for Contractors and Subcontractors

FDA officials will provide training regarding the FDA Tobacco Compliance Check Inspection Program to the Program Coordinator, Backup Program Coordinator, and Inspectors. Inspectors must be commissioned by FDA before accessing any training materials. The Program

Coordinator shall ensure that all Inspectors have taken and passed the FDA Tobacco Compliance Check Inspection Program Training before beginning initial inspections. Out-of-state travel is not anticipated for FDA-provided inspector training. Training will be conducted via teleconference or online learning management system. The Contractor must ensure that all parts of the FDA Tobacco Compliance Check Inspection Program training are followed as prescribed.

FDA will conduct mandatory quarterly conference calls/training (approximately 2 hours each) for the Program Coordinator and Backup Program Coordinator to review topics related to inspection procedures, new policies, and contractual updates. Additional conference calls may be scheduled as necessary.

FDA will provide two mandatory virtual refresher trainings to Inspectors each year to review topics related to inspection procedures and new policies that will last approximately 1 hour each.

When identified by the Contractor or FDA , inspectors that make multiple and/or repeated procedural errors shall undergo additional training .The Contractor shall provide FDA with a plan within two business days on how it intends to address inspector errors that are identified. The Contractor shall notify FDA when this issue resolved.

No inspection participant may conduct inspections prior to passing FDA provided training. Additional training from FDA may be provided to the Contractor upon the Contractor's request in order to refresh Contractor knowledge of the retail inspection program.

2. Training for Minors

The Contractor shall train minors and shall institute its own training methods in addition to ensuring that each minor completes the required FDA minor module. The Contractor's training program may include mock undercover buy inspections so newly recruited Minors may observe experienced Minors conduct undercover buy inspections before conducting them on their own. Each Minor must complete the required FDA minor training prior to conducting any inspections. Inspectors shall review each inspection with the minor and advise them of any necessary corrections prior to moving to the next inspection.

3. Program Coordinator In-Person Training

FDA may conduct in-person training for Program Coordinators during the base year or option years of this contract. If held, this training is expected to cover two to three full working days and be held in the Washington, D.C. metropolitan area. If offered by FDA, it is mandatory that the Program Coordinator attend this in-person training. The attendance of the Backup Program Coordinator(s) is highly recommended by FDA. FDA anticipates that this training will occur approximately every three years.

C.1.3. IDENTIFICATION AND SELECTION OF RETAILERS

1. **Retail Outlet List**

A retailer is any person, government, or entity who sells regulated tobacco products to individuals for personal consumption, or who operates a facility where vending machines or self-

service displays of tobacco products are present, as referenced in 900(14) of the FD&C Act. A retail outlet is a location where a retailer sells tobacco products or operates a self-service display of tobacco products, which includes vending machines. These retail outlets may include, but are not limited to, supermarkets, convenience stores, bars, clubs, restaurants, gas stations, newsstands, mobile food trucks, or mobile carts that sell tobacco products.

FDA currently possesses a list of the tobacco retailers located in the subject jurisdiction and will provide it to the contractor on award. Within 60 days after award, the Contractor shall assess the FDA supplied electronic list of retail outlets and revise and/or add establishments to create an accurate, non-duplicative, and complete list. The source(s) used to assess and revise the list and description of whether the list is considered to be comprehensive must be included. A description and the results of any coverage studies completed or other methods used to assess the accuracy and completeness of the list of retail outlets must also be included. The Contractor shall confirm that the retail outlet list does not contain any retail outlets that are located on Tribal Land. The retail outlet list must contain, at a minimum, the retail outlet name, physical address (including city, state or territory, and zip code), and unique ID number (assigned by FDA when added to TIMS). The Contractor is responsible for making changes to their retail outlet list contained in the TIMS system, after consulting with FDA and obtaining guidance from FDA. The Contractor shall provide lists with additional establishments (after confirming that the establishments are not already in TIMS) to FDA throughout the Contract period of performance. The Contractor shall provide updates to the retail outlet list to FDA Quarterly in the corresponding Monthly Reports or certify that the current retail outlet list is the most up-to-date list available, and all corrections have been previously submitted. See Attachment 2 for the current required format for the retail outlet list. The format is subject to change based on program needs.

Entities Not Included on Retail Outlet Lists

Entities discovered to sell regulated tobacco products but are not in the TIMS database shall be added to TIMS. Before the entity is added, the Program Coordinator shall verify that the entity:

- Sells regulated tobacco products;
- Is not already in the TIMS database; and
- Is open for business.

2. Selection of Retailers for Contractor Directed Inspections

For Contractor Directed inspections, the Contractor shall decide which retail outlets shall be inspected from the list of retail outlets in TIMS. In identifying which retailers to inspect in each jurisdiction, the Contractor shall consider several factors, including areas that are considered at higher risk for regulatory violations, such as: (1) areas with high rates of youth cigarette smokers, (2) areas where youth report easy access to cigarettes, (3) areas located in close proximity to middle and high schools, or (4) regions with lower socioeconomic populations (historically associated with market targeting). For retailers that are found to be non-violative during Contractor Directed inspections, the Contractor shall not conduct more than one inspection of said retailer in a twelve month period.

The Contractor shall ensure that the commissioned inspectors conduct tobacco compliance check inspections at a variety of different locations (urban, suburban, rural, and racial and ethnic

minority communities) and outlet types throughout the jurisdiction. The Contractor shall ensure that retail outlets in racial and ethnic minority communities are covered during the Contract period. This requirement is consistent with the statutory requirements set out in Section 105 of the Tobacco Control Act, which requires FDA to enforce the "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents" on promotion and advertising of menthol and other cigarettes targeted to youth, including youth in racial and ethnic minority communities.

The Contractor shall also provide the FDA COR with any information, as it becomes available, regarding any entities or events that may be considered a "Qualified Adult Only Facility" or any entities that are distributing free samples of smokeless tobacco products or other tobacco products for advertising, marketing or promotional purposes as defined in 21 CFR Part 1140.16(d)(2)(iii).

For each retailer inspected, the Contractor shall ensure the inspector records all inspectional information pertaining to that visit before beginning the next inspection or by the end of the day, if it is the last inspection of the day.

The Contractor shall conduct inspections in the jurisdiction evenly distributed throughout the year for the base period and each subsequent option period.

C.1.4. FDA'S TOBACCO INSPECTION MANAGEMENT SYSTEM (TIMS)

FDA's Tobacco Inspection Management System (TIMS) can work in conjunction with a specific handheld device that shall be provided by FDA and allows for the electronic transmission of information. FDA will not consider contractor provided devices. The TIMS Application provides FDA and Contractors with a front-end web interface for accessing and managing FDA tobacco inspection assignment information and related processes. The handheld device currently provided to Inspectors by FDA is an iPhone. FDA will provide the service plans for these devices.

The Contractor shall notify the FDA COR and the TIMS Helpdesk immediately of any hardware and software problems so that FDA can work with the Contractor to resolve them.

The Program Coordinator is responsible for ensuring that Inspectors submit data to FDA as defined in C.1.5 through C.1.7, below. FDA will work with the Contractor to ensure designated staff is able to access TIMS and inspection assignments, submit inspection information to FDA, and access appropriate data for the Contractor's inspectional and reporting needs.

Beyond what is publicly available on the FDA external website, no other data resulting from Federal tobacco retailer compliance check inspections, including data in TIMS, may be shared with entities outside of FDA. The prohibition of the release, publication, or disclosure of non-public information, except under specific circumstances, is covered under FDA Form 3398, Commitment to Protect Non-Public Information Agreement. All Contractor staff who are directly involved in the inspection program or have access to data gathered under this program must sign the FDA Form 3398.

C.1.5. COMPLIANCE CHECK INSPECTIONS

A. Overview of General Inspection Procedures

The Contractor shall arrange tobacco compliance check inspections of retailers that sell or advertise tobacco products to determine whether those retailers are complying with the Tobacco Control Act and the implementing regulations (See Section B.1.C.). Generally, the Contractor shall carry out two (2) types of tobacco compliance check inspection assignments: (1) undercover buy assignments, to determine a retailer's compliance with age and photo identification requirements; and (2) advertising and labeling, to cover other provisions of the Tobacco Control Act. In some instances, FDA may request that both types of assignments be conducted within a short timeframe (specified during training) of each other at a particular retail outlet.

Of the Contractor Directed inspections the Contractor performs under this contract, 100% shall be undercover buy assignments.

The Contractor shall assign compliance check inspection assignments of identified retail outlets to Inspectors via TIMS. FDA may request that certain retail outlets or areas be inspected. FDA may also ask the Contractor to ensure compliance check inspections are conducted in specific areas at certain times.

The Contractor shall ensure each Inspector conducts and documents each assignment according to FDA protocol (provided during training). Documentation of the inspection requires the Inspector to: (1) record the findings on a compliance check inspection form, which will be provided by FDA via the handheld device; (2) collect physical evidence (e.g., tobacco products purchased by the minor) or take photographs using the handheld device; and (3) record any additional observations as instructed by FDA.

If the retail outlet is found to be out of compliance, FDA may request assistance from the Contractor in verifying the ownership information of a particular retail outlet and may need inspectors to return to the retail outlet to obtain further information and evidence.

The Contractor shall ensure proper collection, handling, sealing, documentation, storage, and submission of evidence pursuant to FDA protocol to ensure that evidence is maintained in a manner that shall allow FDA to use the evidence to support an enforcement action. The Contractor shall store evidence for the duration of the contract and shall perform a single transfer of all evidence to FDA or an FDA contractor prior to the end of the contract.

The Program Coordinator shall review the results of certain assignments in accordance with FDA protocols and submit the results to FDA via TIMS.

The Contractor shall ensure the procedures and standards for data and evidence security is followed. This shall include but is not limited to ensuring anonymity of compliance check inspection participants, confidentiality of data and evidence collection, and transmission and storage of property and evidence. Further details regarding the inspection procedures shall be provided in the FDA Retail Inspection Program training once staff associated with the Contract have a background check and have been cleared and/or commissioned.

1. FDA Directed and Contractor Directed Undercover Buy Inspections

Section C.1 indicates the number of FDA directed undercover buy inspections and the number of contractor directed undercover buy inspections for each jurisdiction. The Contractor shall ensure that FDA protocol for conducting compliance check inspections is followed. Generally, undercover buy inspections shall be conducted by teams comprised of an Inspector and a Minor. The Minor must be supervised at all times, with limited exceptions. It is FDA's preference that Inspectors accompany Minors into the retail establishment during undercover buy inspections. Inspectors shall position themselves so that they can observe Minors during the entire undercover buy inspection to ensure that they can complete a narrative report attesting that they have witnessed the violation. An inspector shall only conduct an unobserved undercover buy assignment (where the inspector cannot see the transaction) if the inspector's presence would compromise the inspection. Minors are required to complete narrative reports for all inspections they conducted.

A representative mix of 16 and 17 year old Minors who look their age should be used. The Minor group should also reflect a representative mix of male and female Minors and should reflect the racial/ethnic composition of the population where the undercover buy is conducted.

The Contractor shall ensure that Minors used in the undercover buy inspections are not related to the Inspectors conducting the inspection of a specific retail outlet or the Chaperone, if one is present. The Contractor shall ensure that undercover buy inspections using Minors are conducted during the hours deemed safe by the Program Coordinator.

If it is required under the law of the Contractor's jurisdiction to issue a citation after a violation, the Contractor shall not issue the citation until all compliance check inspections for that day are completed and the Minor is returned to his/her proper end location. However, if two Inspectors (or an Inspector and a chaperone) are used for an undercover buy inspection, one Inspector may issue the jurisdiction's required citation after the minor is returned to his/her proper end location, or removed from the retail outlet and under the supervision of the second Inspector (or chaperone). The Contractor shall take every precaution to ensure the safety of the minor. Enforcement of the jurisdictional violation will not be funded under this Contract, including the issuing of a mandated citation.

The Contractor shall conduct no more than one Contractor Directed Undercover Buy inspections at a particular retail outlet in a year.

2. FDA Directed Advertising and Labeling Inspections

The Contractor shall conduct compliance check inspections to determine retailer compliance with the provisions of the Tobacco Control Act and the implementing regulations, other than the age and photo identification requirements. The Contractor shall conduct advertising and labeling inspections separately from the undercover buy assignments. The Contractor shall develop a system to allow an Inspector to purchase a potentially violative tobacco product during an advertising and labeling inspection. A Minor shall not accompany an Inspector during an advertising and labeling inspection. Inspectors will be required to provide his/her FDA credentials during this type of compliance check assignment. FDA will assign all Advertising and Labeling inspections and will provide a timeframe for completion of assignments. If both an Advertising and Labeling and Undercover Buy inspection have been assigned by FDA, the Advertising and Labeling assignment should be completed first. All inspections shall be completed within 90 days. Additionally, 15% shall be completed within 30 days and 10% shall

be completed within 5 days of assignment. Contractor may be required to conduct hand delivery of documents to a retailer rather than conduct a compliance check inspection. All A&L assignments that must be completed within 5 days will require hand delivery of documents or an abbreviated inspection to determine whether the establishment is selling tobacco products. Up to 20% of these inspections will require the contractor to develop a system to allow an Inspector to purchase a potentially violative tobacco product.

3. Data Transmission

FDA will supply the Contractor with laptops to designated Program employees and handheld devices to Inspectors. The Contractor shall ensure inspectors use these devices to record compliance check inspection data and manage compliance check inspection work.

The Contractor shall ensure inspectors submit the results of each compliance check inspection at a minimum at the end of each inspection day for review.

C.1.6. REVIEWING COMPLIANCE CHECK INSPECTION RESULTS AND ASSISTING WITH ENFORCEMENT ACTIONS

The Program Coordinator shall review the results of compliance check inspections to ensure the quality and completeness of the evidence. All compliance check related work shall be performed by the program coordinator or back-up program coordinator on an FDA-provided laptop. Within 48 hours of receiving the compliance check inspection assignment results from the Inspector, the Program Coordinator shall submit a recommendation for the inspection results in their queue and make appropriate updates to establishment records electronically through the TIMS system to FDA.

Although a retailer may be in violation of the laws of a jurisdiction in addition to federal violations, the Contractor's recommendations to FDA shall be based solely on violations of the Tobacco Control Act and the implementing regulations.

The results of completed retailer compliance check inspections are available to the public on FDA's website.

1. Compliance Check Inspection Inquiries

If the inspection data or evidence submitted by the Program Coordinator requires clarification or is not sufficient, FDA may require that the Program Coordinator and/or the Inspector provide clarification and/or collect additional evidence to complete the review of an inspection.

Within 48 hours of receiving a request FDA, the Program Coordinator shall provide the FDA Requestor with information about a compliance check inspection and investigation unless citing extenuating circumstances.

2. FDA Enforcement Actions

FDA reviews the compliance check inspection recommendations and the accompanying evidence submitted by the Contractor.

If FDA determines that enforcement action shall be taken against a retailer, FDA has several enforcement tools that it may use, including: (1) issuance of a Warning Letter, (2) imposing an administrative civil money penalty (CMP) or a No-Tobacco-Sale Order (NTSO), (3) initiating judicial actions, such as a seizure or injunction, or (4) initiating criminal prosecution.

If FDA takes enforcement action, the Contractor shall assist FDA with any needed follow-up related to the compliance check inspections. For example, the Contractor shall be responsible for securing prompt and continuing cooperation from witnesses. In addition, if requested, the Inspector and Minor must remain available to testify as a witness and provide oral testimony following any compliance check inspection in support of an FDA enforcement action and shall provide such testimony upon request.

The Contractor shall maintain all original inspection records and evidence in its files for FDA for the length of the contract. If the tobacco compliance check inspection Contract with the Contractor expires or is not continued before the five-year period, the COR will provide instructions for transfer of these records and evidence. These files, which are considered FDA files subject to Federal Freedom of Information Act (FOIA) requirements, shall be secured and maintained separate and apart from other files. These records include all documents and items created and collected during and after Compliance Check Inspections, including Compliance Check Inspection Forms, evidence, photographs, etc.

Apart from FDA enforcement actions for violations of the Tobacco Control Act and its implementing regulations, jurisdictional enforcement actions may be pursued against retail outlets that are found to have also violated the law of that jurisdiction. These efforts must be coordinated with the FDA COR and not compromise FDA's compliance check inspection procedures, data, or evidence. Additionally, the Contractor shall furnish information regarding retailer compliance with the jurisdiction's laws, including jurisdictional enforcement actions, where violations are found during FDA inspections, as soon as practicable after inspections are completed.

C.1.7 CONTRACT TRANSITION OUT

The Contractor shall initiate the transition out of contracted activities and services to the Government thirty (30) days prior to the conclusion of the contract.

The Contractor shall gather and return if necessary the following items using FDA-provided shipping label(s):

- FDA issued iPhones with each phone's accessories (including cases, chargers, and/or styluses) from each inspector with a list of the inventory.
- Physical evidence and associated inspections records (including assignment number) with a completed inventory log.
- All files pertaining to minors and inspectors.
- All government furnished equipment and any other equipment purchased with government funds.
- Regulatory notebooks, properly labeled based on FDA provided protocol and procedures.
- Unused FDA materials to include but not limited to Form FDA 482 and evidence bags.

The Contractor shall provide the completed inventory log of physical evidence and FDA-issued

iPhones to the COR with the date that the packages are being shipped to FDA.

C.1.8. QUALITY CONTROL PLAN

The Contractor shall develop and maintain a quality control plan that lists specific actions that will be performed to assure the quality of the Contractor's work as well as the frequency of those actions and the individual to whom those actions are assigned. Revised quality control plans shall be submitted to the COR within 30 days of any changes or deviations to the original Quality Control Plan submitted with the proposal. The Quality Control Plan shall be used to monitor Contractor performance and to ensure that the quality of the information submitted is complete and accurate. The Contractor is responsible for implementing a plan to ensure that:

- FDA funds under this contract are only used for FDA tobacco enforcement activities. The plan shall include, but is not limited to describing how:
    - Time dedicated to contract work is recorded.
    - An inventory of Government-furnished equipment and equipment purchased in support of the contract is established and maintained.
- Evidence is properly collected, documented, and stored in a location accessible only by program staff.
- The number of incomplete or inaccurate submissions and/or evidence documentation is minimized. The plan shall include, but is not limited to describing how:
    - Areas needing improvement will be identified and remedied.
    - Corrective actions will be implemented and communicated to FDA.
- All communications concerning compliance check inspection procedures are received disseminated timely and followed by Program employees including inspectors in the field.
- The Contractor provides required submissions within the timeframes outlined in the contract and responds to FDA inquiries.
- The Contractor performs inspections that follow the policies and procedures as documented by FDA during initial training, refresher training, and through correspondence, and provides a plan for coming into compliance any time inspections do not meet these standards.
- All Program employees:
    - Have documented initial training (and required documentation for Minors);
    - Remain knowledgeable about current procedures; and
    - Abide by Program changes needed to maintain accountability, enforcement, and efficiency of Program operations.

Upon notification by the FDA COR of a problem involving incomplete or inaccurate submissions or evidence documentation, the Contractor must acknowledge the issue, determine the cause, take appropriate corrective action, and notify the FDA COR within one week of such corrective action.

The Contractor shall abide by Program changes needed to maintain efficiency of Program operations and accuracy of compliance check inspection data and evidence. Such changes may include, but are not limited to, compliance check inspection procedures, evidence collection, training, report submissions, and IT system improvements.

C.1.9. MONTHLY REPORT

The Contractor shall submit a Monthly Report to the COR by the 10th of the following month using the template in Attachment 4. A Monthly Report is a quantitative description of overall progress and applicable supporting data in sufficient detail to comprehensively explain progress to date. Appropriate format and topics include:

Cover Page

1. Contract Number and Title
2. Type of report, sequence number and period being covered
3. Contractor's Name and Address
4. Author
5. Date of report

Section I

1. Total number of inspections performed for monthly performance period, and total number of inspections performed to date.
2. Updates to the retail outlet list or certification that the current outlet list is the most up to date list, and all corrections have been entered into TIMS.
3. Number of retail outlets that were eliminated by prescreening, both cumulative and in this quarter.
4. Number of follow-up FDA questions answered concerning compliance check inspections, and number pending and reasons why.
5. List of new employees and employees who have left the program.
6. Media coverage, contact, and/or inquiries, if any.
7. Dates on which Inspectors received FDA training and updates.
8. Description of the jurisdiction's Synar program and how it is coordinated with work under this Contract per quarter, if at all.
9. Description of any non-FDA tobacco control programs in the Contractor's Jurisdiction and how they are coordinated with work under this Contract, if at all.
10. Description of retail outlet inspectional coverage plan.
11. Description of retail outlet inspectional coverage plan for the next quarter.
12. Total number (and percentage) of retail outlets inspected in racial and ethnic minority communities for the current period and to date
13. Description of how retail outlets in racial and ethnic minority communities will be covered in the next month.
14. Total number (and percentage) of retail outlets inspected in areas that are in close proximity to where there is a high concentration of youth (e.g., schools, recreation centers, etc.).
15. Description of retail outlet inspectional coverage plan in areas that are in close proximity to where there is a high concentration of youth (e.g., schools, recreational centers, etc.
16. Description of Contractor's program for the protection, preservation and maintenance of all Government property, recent procedures to educate their employees concerning individual responsibilities for Government property, and recent efforts to monitor and assess the Contractor's property control system.

17. Feedback regarding the use of handheld devices and other hardware, TIMS, and the online compliance check inspection process.
18. Feedback regarding the FDA program in general, including issues or concerns.

Monthly Report - Section II

Financial Information shall be submitted for each major task or line item cost. Data shall include but is not limited to:

1. The total estimated cost budgeted (excluding fee)
2. The estimated cost expended during the current reporting period
3. Identification of direct labor hours of prime contractor, subcontractors and consultants (as applicable)
4. Total project to date expenditures
5. Total funds remaining

Monthly Report - Section III

General discussion to include any issues, concerns or recommendations that the contractor may have to offer.

SECTION D – PACKAGING AND MARKING

D.1 PACKAGING

All deliverables shall be preserved, packaged, and packed in accordance with normal commercial practices to meet the packing requirements of the carrier including that which is necessary to prevent deterioration and damages due to the hazards of shipping, handling, and storing. If the Contractor submits deliverables electronically, the title of the document and contract number shall be identified in the subject line of the email.

D.2 MARKING

Each package/container shall be delivered to the COR at the address in Section G.1.B and shall be clearly marked as follows:

A. Name of Contractor;
B. Contract Number;
C. Description of Items Contained Therein; and
D. Consignee's Name, Address, telephone number, and email address.

SECTION E - INSPECTION AND ACCEPTANCE

E.1 INSPECTION AND ACCEPTANCE

The COR, as a duly authorized representative of the Contracting Officer, shall assume the responsibilities for monitoring the Contractor's performance, evaluating the quality of services provided and performing the final inspection and acceptance of all deliverables. Unless otherwise requested, deliverables shall be sent to the Contracting Officer and COR.

E.2 FAR 52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This Contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at www.acquisition.gov/far.

FAR Clause No.	Date	Title
52.246-5	Apr 1984	Inspection of Services - Cost Reimbursement

E.3 INSPECTION ACCEPTABILITY CRITERIA

The contractor shall receive payment for inspections where an inspection team visits a retail establishment to conduct a compliance check inspection to observe and document a retailer's operational status and compliance with the requirements of the Tobacco Control Act and submits the required findings to FDA within the required timeframe and only if the following inspection acceptability criteria are met:

A. Undercover Buy Assignments

1. The minor must be 16 or 17 years old at the time the inspection is conducted.

2. Each inspection must be completed before the inspector starts a new inspection; this includes completion of all documentation

3. All inspections must include at least one (1) on site photograph of the establishment that provides a clear representation of the establishment or an explanation as to why a photograph could not be taken.

B. Advertising and Labeling Assignments

1. The inspection record for every complete assignment must include a photograph or scanned copy of a properly issued and signed Form FDA 482 or an explanation within the inspection assignment for the absence of the FDA 482.

2. Each inspection must be completed before the inspector starts a new inspection; this includes completion of all documentation.

3. If there are any potentially violative items, the inspector must take at least one (1) photograph of the item that establishes where it is in the store or explain why such a photograph could not be taken within the inspection.

4. All inspections must include one (1) photograph of the establishment to include

the signage and a clear representation of the establishment's operational status or an explanation as to why a photograph could not be taken.

Failure to meet the specified criteria and terms of the contract will result in the inspection being considered unacceptable for payment. It is the Contractor's responsibility to confirm that all inspections submitted for payment meet the criteria described in this section.

SECTION F – DELIVERIES OR PERFORMANCE

F.1 PERIOD OF PERFORMANCE

The Period of Performance for this Contract shall be comprised of a 12-month base period and two (2) 12-month option periods.

F.2 PERIOD OF PERFORMANCE – OPTION PERIODS

If the Government exercises its option pursuant to FAR 52.217-9, Option to Extend the Term of the
Contract, the period of performance will be increased as listed below:

Option Period I: *Shall be completed at contract award
Option Period II: *Shall be completed at contract award

The option may be exercised unilaterally in accordance with FAR 52.217-9, Option to Extend the Term of the Contract (Mar 2000).

The Government anticipates awarding contracts prior to September 30, 2017.

F.3 DELIVERABLES

All deliverables required by this Contract shall be delivered via e-mail to the COR except where indicated that the Contracting Officer (CO)/Contract Specialist (CS), and the COR receive copies. The description of each deliverable is identified in Section A below. All deliverables shall be subject to the inspection and acceptance of the COR.

REFERENCE #	DELIVERABLES	TIMELINE/DUE DATE
C.1.1.	Names of individuals for commissioning, security contact information and any other documentation FDA deems necessary for commissioning	Within 21 days after award and as new individuals are identified ***Description 1***
C.1.1.	Minor information	At least 14 days before the Minor begins inspecting ***Description 2***

C.1.1.	Notification of changes to information for Program Coordinator, Backup Program Coordinator, Inspectors, Administrative Assistants,	At least 14 days before beginning work on this contract ***Description 3***
C.1.2.	Completion of training provided by FDA	Within 14 days before conducting inspections ***Description 4***
C.1.3.	Retail outlet list or updates to list	Within 21 days after award and provide updates as available ***Description 5***
C.1.3.	Plan for retailers to be inspected	Include in Monthly Reports ***Description 6***
C.1.5.	Inspection Data in TIMS	Within 48 hours of receipt from Inspector ***Description 7***
C.1.5.	Compliance Check Inspection Inquiries	Within 48 hours of receipt of request from FDA ***Description 8***
C.1.9.	Monthly Reports to CO and COR	10th business day of the following month ***Description 9***
G.3	Invoice to CO and COR	20th business day of the following month ***Description 10***
C.1.8.	Quality Control Plan to CO and COR	With Proposal and at least 30 days prior to any changes ***Description 11***
H.1	Contractor's Commitment to Protect Non-Public Information to CO and COR	Within 21 days after award and prior to commencement of any work under this contract ***Description 12***
H.1	Annual Briefing Reports to CO and COR	Within 10 days of conducting annual briefing ***Description 13***
F - Description 13	Annual Inspector/Minor Contact information	Annually ***Description 14***
F - Description 14	Individual Inspector/Minor Contact information	Within five (5) days from request by FDA ***Description 15***

The Contractor shall submit the deliverables to the CS, CO, and COR's e-mail or mailing addresses (as required) which are specified in section G.1.

A. DESCRIPTION OF DELIVERABLES:

Description 1: Commissioned Officer Information - The Contractor shall provide the COR with all necessary materials for Commissioning, including a list that contains the following information for each potential Commissioned Officer: Full Legal Name, expected role in the program, full work address, work number, cell number, and email address. The Contractor shall notify the FDA COR of any changes of employment status and return the Commissioned Officers credentials within 10 days of the Officer no longer working under this Contract.

The Contractor must submit contact information for the person(s) or entity most familiar with their agency's background investigation procedure. If applicable, the Contractor must also provide security contact information for individuals that the Contractor intends to subcontract.

Description 2: Minor Information – Once the Contractor has access to TIMS, the Contractor shall update TIMS with each Minor's unique identification number, gender, and date of birth.

Description 3: Notification of Changes - The Contractor shall inform the COR when there are any changes to the information for Program Coordinator, Backup Program Coordinator, Inspectors, Administrative Assistants, Chaperones, Commissioned Officers, or Minors (e.g., phone number, e-mail address, status, change of personnel, etc.).

Description 4: Completion of Initial Training - The Contractor shall inform the COR when Inspectors are trained and ready to begin conducting compliance check inspections.

Description 5: Retail Outlet List - The Contractor shall supply FDA with a detailed, accurate, and comprehensive electronic list of retail outlets that sell covered tobacco products in the Contractor's jurisdiction. The source(s) of the list and why the list is considered to be comprehensive must be included. A description and results of any coverage studies completed or other methods used to assess the accuracy and completeness of the list of tobacco retail outlets must also be included. A Contractor must confirm that its retail outlet list does not contain any retail outlets that are located in Indian Country. The retail outlet list must contain, at a minimum, the retail outlet name (the outlets trade name or Doing Business As name is required and its legal name is optional), physical address, mailing address (including zip codes), unique ID number, as well as the name and mailing address of the legal owner(s) of the retail outlet, if available.

When new lists become available, or when the Contractor learns of retail outlets that should be added to the lists, the Contractor is responsible for updating the retail outlet list in TIMS. Each quarter, the Contractor shall certify to FDA that the current retail outlet list is the most up to date list available.

> ***Current Contractors*** – If current FDA Contractors have retail outlet information already uploaded into TIMS, this information will remain in TIMS. Current Contractors are not required to submit a new retail outlet list. However, Contractors will still need to follow all other requirements related to Section C.2.C.1, Retail Outlet List, such as providing updated retailer information as it becomes available and assisting FDA with researching ownership information.

Description 6: Plan for Retailers to be Inspected - The Contractor shall supply FDA with an explanation of how it complied with its plan to ensure that compliance check inspections are

conducted at a variety of different locations (urban, suburban, rural, and racial and ethnic minority communities) and outlet types throughout its jurisdiction. The Contractor shall also provide any changes to its plan.

Description 7: Inspection Data **-** The Program Coordinator shall submit the inspection assignment results and recommendation electronically through TIMS to the COR within 48 hours of receiving the inspection assignment results from the Inspector.

Description 8: Compliance Check Inspection Inquiries **-** If the inspection data and evidence submitted by the Contractor requires clarification or is not sufficient, the COR may require that the Program Coordinator and/or the Inspector provide clarification and/or collect additional evidence to complete the closeout of an inspection. The Contractor shall provide the COR with this additional information within 48 hours of receipt of request from FDA.

Description 9: Monthly Reports - A Monthly Report is a quantitative description of overall progress and applicable supporting data in sufficient detail to comprehensively explain progress to date. For appropriate topics see Section C.1.9. The Contractor shall submit Monthly Reports to the COR using the template in Section J, Attachment 3.

Description 10: Invoice – An invoice is a submission for payment of completed inspections and service provided that correspond to data provided in the Monthly Report. For appropriate topics see Section G.3. The Contractor shall submit Monthly Reports to the CO and COR using the template in Section J, Attachment 7.

Description 11: Quality Control Plan **-** The Contractor shall develop, implement, and maintain a Quality Control Plan in accordance with the requirements of C.1.8.

Description 12: Access To Non-Public Information - All Contractor and Subcontractor employees are required to sign the Form FDA 3398 – Commitment to Protect Non- Public Information Agreement provided as an attachment to this contract (*See* Section J, Attachment 4). If a person who has signed this agreement resigns, is dismissed, or is otherwise no longer working on this contract, the Contractor shall notify the Contracting Officer and COR. Any new Contractor or subcontractor employee assigned to this contract shall sign the Agreement. The signed Agreement shall be submitted to the Contracting Officer and COR prior to commencement of any work under this contract.

Description 13: Annual Briefing Reports - The Contractor shall brief all employees, subcontractors and consultants regarding the sensitivity of the information to be handled under the contract and of the responsibility to protect it. The briefing shall stress that the information is non-public and shall not be disclosed to any unauthorized source. The Contractor shall conduct an updated briefing annually and shall submit a report, electronically or hard copy, to the Contracting Officer and COR within ten (10) days after the briefing. The report shall include: an outline of the briefing, a copy of any briefing materials, date briefing was conducted and the names of the attendees.

Description 14: Annual Update of Inspector/Minor Information – The contractor shall provide an updated comprehensive list of contact information for all current inspectors and minors as well as inspectors and minors that have been employed within the previous five years.

Description 15: ***Individual Inspector/Minor Information*** - If requested by FDA, the Contractor shall, within 5 days of the request, submit to FDA the current contact information for Inspectors and Minors that have left the program.

F.4 PLACE OF DELIVERY

Place of delivery will be in multiple States (reference the chart in Section C.1)

F.5. FAR 52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This Contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at www.acquisition.gov/far.

FAR Clause No.	Date	Title
52.242-15	Aug 1989	Stop Work Order

SECTION G - CONTRACT ADMINISTRATION DATA

G.1 AUTHORITIES OF GOVERNMENT PERSONNEL

The Contractor shall share sufficient information throughout the life of the contract that the FDA maintains oversight and control of all inspection activities, and that the FDA may redirect the Contractor's activities, as deemed necessary or otherwise in the best interests of the FDA. The following individuals shall be the Government's points of contact during performance of the Contract:

A. CONTRACTING OFFICER/CONTRACT SPECIALIST

All communications pertaining to contractual and/or administrative matters under the Contract should be addressed to the Contract Specialist. The Contract Specialist assigned to this Contract is (*TBD). All contract administration shall be performed by the Contract Specialist, (*TBD), FDA/OC/OAGS, 5630 Fishers Lane, Rockville, Maryland 20857. (*TBD) can be reached at TBD or electronically at _____TBD_____@fda.hhs.gov. The alternate point of contact for this contract is TBD @fda.hhs.gov.

B. COR APPOINTMENT AND AUTHORITY

The COR assigned to this Contract is:
Shawnte Adams
Phone: 301-796-7277

Email: Shawnte.Adams@fda.hhs.gov

Performance of work under this Contract must be subject to the technical direction of the COR identified above, or a representative designated in writing. The term "technical direction"

includes, without limitation, direction to the Contractor that directs or redirects the labor effort, shifts the work between work areas or locations, fills in details and otherwise serves to ensure that tasks outlined in the work statement are accomplished satisfactorily.

Technical direction must be within the scope of the specification(s)/work statement.

The COR does not have authority to issue technical direction that:

- Constitutes a change of assignment or additional work outside the specification(s)/statement of work;
- Constitutes a change as defined in the clause entitled "Changes";
- In any manner causes an increase or decrease in the contract price, or the time required for contract performance;
- Changes any of the terms, conditions, or specification(s)/work statement of the Contract;
- Interferes with the Contractor's right to perform under the terms and conditions of the Contract; or
- Directs, supervises or otherwise controls the actions of the Contractor's employees.

Technical direction may be oral or in writing. The COR shall confirm oral direction in writing within five (5) business days, with a copy to the Contracting Officer.

The Contractor shall proceed promptly with performance resulting from the technical direction issued by the COR. If, in the opinion of the Contractor, any direction of the COR, or his/her designee, does not fall within the scope of his/her authority, the Contractor shall immediately notify the Contracting Officer no later than the beginning of the next Government business day.

Failure of the Contractor and the Contracting Officer to agree that technical direction is within the scope of the Contract shall be subject to the terms of the FAR Clause 52.233-1, Disputes.

The type of actions within the purview of the COR's authority is to assure that the Contractor performs the technical requirements of the Contract, and to notify both the Contractor and the Contracting Officer of any deficiencies observed. A letter of designation shall be issued to both the COR and the Contractor at the time of the Contract award setting forth in full the responsibilities and limitations of the COR.

G.2 HHSAR 352.237-75 KEY PERSONNEL (DEC 2015)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to the contractor voluntarily diverting any of the specified individuals to other programs or contracts the Contractor shall notify the Contracting Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the contractor is terminated for cause or separates from the contractor voluntarily with less than thirty days notice, the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the Contracting Officer. The contract will be modified to add or delete key personnel as necessary to reflect the agreement of the parties.

The Contractor must receive Contracting Officer's Authorization (COA) prior to assigning the Program Coordinator and Backup Program Coordinator to this Contract.

The individuals cited below are key personnel:

Program Coordinator

Name:	***shall be identified at contract award.**
Title:	Program Coordinator
Email Address:	_____
Telephone:	_____
Mailing Address:	_____
	_____
	_____

Backup Program Coordinator

Name:	***shall be identified at contract award.**
Title:	Backup Program Coordinator
Email Address:	_____
Telephone:	_____
Mailing Address:	_____
	_____

G.3 INVOICE INSTRUCTIONS

The Contractor shall submit invoices no later than the 20th day of the following month after receipt and acceptance of all contractual deliverables scheduled for submission during the period. Vouchers/Invoices shall not be approved without submission of the Monthly Report. The invoice shall be submitted using the Template provided in Section J, Attachment 7 and shall include the cost information outlined in Sections G.4, G.5, and G.6.A for inspection, travel, and program management expenses.

B. PAYMENT BY ELECTRONIC FUNDS TRANSFER

The Contractor shall submit vouchers or invoices in accordance with the FAR 52.232-25, Prompt Payment, and FAR 52.232-33, Payments by Electronic Funds Transfer – System for Award Management. The Contractor is responsible for registering and remaining active in the Central Contractor Registration database at www.ccr.gov. Payment shall be made to the Contractor's financial institution designated in the Contractor's System for Award Management Registration.

The Contractor shall designate a financial institution for receipt of electronic funds transfer payment. The designation shall be submitted in writing to the finance office at the following address:

Office of Financial Services
Food and Drug Administration
10903 New Hampshire Ave
WO32 - Second Floor
MAIL HUB 2145
Silver Spring, MD 20993-0002
Attn: Vendor Payments
(301) 827-3745
Email address: FDAVendorPaymentsTeam@fda.gov

Questions regarding invoice payments shall be directed to FDA/OFS at FDAVendorPaymentsTeam@fda.gov or call (301) 827-3745.

G.4 FDA INVOICE SUBMISSION

FDA Two-Way Match Invoicing Procedures

A. The contractor shall submit all invoices to:

U.S. FOOD AND DRUG ADMINISTRATION

Attn: Vendor Payments
Office of Financial Services
10903 New Hampshire Ave
WO32 - Second Floor
MAIL HUB 2145
Silver Spring, MD 20993-0002

301-827-3742
FDAVendorPaymentsTeam@fda.hhs.gov

*** Acceptable methods of delivery include: E-mail (preferred) and Standard Mail.

B. Invoices submitted under this contract must comply with the requirements set forth in FAR Clauses 52.232-25 (Prompt Payment) and 52.232-33 (Payment by Electronic Funds Transfer - System for Award Management) and/or other applicable FAR clauses specified herein. To constitute a proper invoice, the invoice must be submitted on company letterhead and include each of the following:

(i) Name and address of the contractor;

(ii) Invoice date and invoice number;

(iii) Contract/Order number (including a reference to any base award for Indefinite-Delivery/Indefinite-Quantity Contracts or Blanket Purchase Agreements);

(iv) Description, quantity, unit of measure, unit price, and extended price supplies delivered or services performed, including:
(a) period of performance for which costs are claimed;
(b) itemized travel costs, including origin and destination;
(c) any other supporting information necessary to clarify questionable expenditures;
(d) the contractor shall include the Contract Line Item/Funding line item for each description, quantity, unit of measure, unit price, and extended price supplies delivered or services performed;

(v) Shipping number and date of shipment, including the bill of lading number and weight of shipment if shipped on government bill of lading;

(vi) Terms of any discount for prompt payment offered (Prompt Payment terms other than NET 30);

(vii) Name and address of contractor official to whom payment is to be sent (must be the same as that in the contract or in a proper notice of assignment);

(viii) Name, title, and phone number of person to notify in event of defective invoice;

(ix) Taxpayer Identification Number (TIN);

(x) Electronic funds transfer (EFT) banking information, including routing transit number of the financial institution receiving payment;

(xi) Name and telephone number of the FDA Approving Official (i.e., Contracting Officer (CO) or Contract Specialist (CS), as referenced in the award document);

(xii) Name and telephone number of the FDA Contracting Officer Representative (COR) or other program center/office point of contact, as referenced in the award document;

(xiii) Contractor is required to attach an invoice log addendum to each invoice which shall include, at a minimum, the following information for contract administration and reconciliation purposes:

(a) list of all invoices submitted to date under the subject award, including the following:

(1) invoice number, amount, & date submitted

(2) corresponding payment amount & date received

(b) total amount of all payments received to date under the subject contract or order

(c) and, for definitized contracts or orders only, total estimated amounts yet to be invoiced for the current, active period of performance;

(xiv) Any other information or documentation required by the contract/order award.

C. An electronic invoice is acceptable if submitted in Adobe Acrobat (PDF) format. All items listed in (i) through (xii) of this clause must be included in the electronic invoice. Electronic invoices must be on company letterhead and must contain no ink changes and be legible for printing.

D. Questions regarding invoice payments should be directed to the FDA Payment Office at the e-mail address or phone number provided above in Section A.

G.5 GOVERNMENT FURNISHED PROPERTY (GFP)

It is possible that the Government may provide and deliver electronic handheld devices to the Contractor. It is also possible that the FDA will replace these specific units when updates are made to the software application. The Government will provide 2 laptops to the contractor.

Equipment Return - Upon the departure or reassignment of an Inspector, or upon expiration of the Contract **ALL** IT equipment provided by FDA for the Inspector or Contractor, respectively, shall be returned to the COR within ten (10) days of the inspector's departure.

G.6 CONTROL OF PROPERTY

In addition to the applicable "Government Property" clause in Section I, the Contractor shall comply with the provisions of DHHS publication "Contractor's Guide for Control of Government Property," which is hereby incorporated by reference. The guide is available on the HHS website:
https://web.archive.org/web/20111015213630/http://www.hhs.gov/hhsmanuals/logisticsmanual/Appendix%20Q_HHS%20Contracting%20Guide.pdf

All references in the Guide to the acquisition cost threshold for accountable property are changed to $5,000.

The Contractor shall inventory all accountable Government property and submit a list of that property to the Contracting Officer on commencement of the Contract, usually concurrent with

transfer of the property, annually on the anniversary of contract award, and within 90 days after completion or termination of the Contract.

The inventory list, reflecting each item of accountable property as a separate line item, should contain the following data elements:

1. Barcode/tag number
2. Item name/description
3. Manufacturer's name
4. Manufacturer's model number
5. Manufacturer's serial number
6. Unit cost
7. Date received/inventoried
8. Contract number
9. Remarks (optional)

G.7 REPORT ON ACCESS TO GOVERNMENT PROPERTY

The Contractor shall ensure that all Contractor employees are informed that they are not to use any Government property for personal use. To ensure that the employees are informed of this policy, the Contractor shall submit to the Contracting Officer a monthly report on Access to Government Property. This report shall document and summarize the Contractor's program for the protection, preservation and maintenance of all Government property, procedures to educate their employees concerning individual responsibilities for Government property, and efforts to monitor and assess the Contractor's property control system.

G.8 POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

During the life of this Contract, the Contractor's performance shall be evaluated on an interim and final basis pursuant to FAR 42.15, Contractor Performance Information. The evaluation shall be conducted utilizing the Past Performance Information Retrieval System (PPIRS). The Contractor shall register in the PPIRS upon contract award. The PPIRS may be accessed by the Contractor at http://www.ppirs.gov/.

Interim and final evaluations of Contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluation(s) shall be submitted annually.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, Contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

a. Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through the Contractor Performance Assessment Reporting System (CPARS) web site, which is managed by the Department of Defense (DOD). Details regarding CPARS training and on-line registration can be found at http://www.cpars.csd.disa.mil/.

The registration process requires the Contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the Contractor will be required to identify an alternate contact who will be responsible for notifying the FDA contracting official in the event the primary contact is unavailable to process the evaluation within the required 14-day time frame.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

H.1 ACCESS TO NON-PUBLIC INFORMATION

All persons authorized by FDA to work under this Contract are required to sign Form FDA 3398 – Contractor's Commitment to Protect Non-Public Information Agreement. (*See* Section J, Attachment 4). If a person who has signed this Agreement resigns, is dismissed, or is otherwise no longer working on this Contract, the Contractor shall notify the COR and Contracting Officer within ten (10) days. Any new person assigned to this Contract shall sign the Agreement and shall submit it to the Contracting Officer and COR prior to commencement of any work under this Contract. No person working under this Contract shall be provided or possess non-public information in any form unless written approval and a facility clearance have been granted by the Contracting Officer. The disclosure of any confidential information in violation of the Agreement may be subject to civil or criminal sanctions.

The Contractor and its employees shall exercise the utmost discretion in regard to all matters relating to their duties and functions. They shall not communicate to any person any information known to them by reason of their performance of services under this contract which has not been made public, except in the course of their duties or by written authorization of the Contracting Officer. Furthermore, no article, book, pamphlet, recording, broadcast, speech, television appearance, film, or photographs concerning any aspect of the contract shall be published or disseminated through any media without the prior written authorization of the Contracting Officer. The Contractor shall include the substance of this provision in all contracts for employment and in all subcontracts hereunder.

Briefings

An FDA representative (typically, the COR) shall conduct an orientation briefing for the Contractor/Contractor employees. The briefing shall stress: (1) the importance of protecting non- public information; (2) specified computer/Automated Data Processing requirements as outlined in the DHHS Automated Information Systems Security Program Handbook (copy of handbook available upon request); and (3) the consequences of unauthorized disclosure of non-public information. Briefing updates shall be conducted annually.

The Contractor shall brief all employees, subcontractors, and consultants regarding the sensitivity of the information to be handled under the Contract and of the responsibility to protect it. The briefing shall stress that the information is non-public and shall not be disclosed to any unauthorized source. The Contractor shall conduct an updated briefing annually and shall submit a report to the COR within ten (10) days after the briefing. This report shall include: an outline of the briefing, a copy of any briefing materials, date briefing was conducted and the names of the attendees.

H.2 FDA 1354 PHYSICAL SECURITY REQUIREMENTS FOR RELEASING NON- PUBLIC INFORMATION

Under the provisions of Title 21, United States Code, Section 331(j), the Contractor shall establish and maintain comprehensive security measures for controlling access to non-public information released under a contract involving the processing of such information. This clause applies to the Contractor, any subcontractors, and any consultants. Non-public information shall be released to only those persons authorized under this Contract (authorized persons).

For transmittal of documents the Contractor shall adhere to the following:

- Documents to be transmitted internally shall be transmitted on a person-to-person basis between authorized persons only.

- Documents to be transmitted outside the Contractor's facility shall be double-wrapped with the inner wrapping marked "FDA Privileged Information - Access Controlled." The names and addresses of the sender and addressee shall be typed on both the inner and outer wrappings.
- Documents to be transmitted back to the FDA or to another address designated by the FDA shall be transmitted by the Contractor, by U. S. Registered mail (return receipt requested) or other courier services that track shipments/deliveries.
- A receipt log shall be maintained for all external transmittals: for example, documents transmitted outside the Contractor's facility, documents to be transmitted back to the FDA or to another address designated by the FDA.
- The Contractor shall follow up all transmittals in order to obtain signed receipt within five (5) business days of transmittal. Failure of recipient to furnish such receipt shall be reported to the FDA Physical Security Office within ten (l0) business days of transmittal.

As provided in Section C.2.5, Overview of General Inspection Procedures, the Contractor shall ensure procedures and standards for data and evidence security, including chain of custody are followed. *See* L.3, Proposal Instructions. In addition, Section F, Quality Control Plan, also discusses the need for properly preserving evidence collected. Any evidence collected, must be stored in a secured location, and accessible, if needed, to support an FDA enforcement action. Chain of custody must be maintained. The Contractor shall provide any protocols for controlling the access to non-public information, including inspection data and evidence that have been developed and are currently in use. Lastly, the FDA Training Manual provides that the Program Coordinator is responsible for developing a storage system. The Program Coordinator must ensure that:

- all inspection packages are centrally stored,
- all inspection packages are secured from any tampering, loss, theft, or damage, and
- the storage system is easily searchable so inspection packages are retrievable upon request by FDA.

If the Contractor's facility has a current certification from the Defense Contract Administration Services/Defense Logistics Agency (DCAS/DLA) as a "Secret" or higher classification, such rating will satisfy the FDA security requirements for the Contractor's facility. Loss of such certification during the period of the Contract will be cause for a possible issuance of a Stop Work Order pending review by the FDA's Physical Security Staff of the Contractor's facility. The Contractor shall notify the FDA Physical Security Office in the event their DCAS/DLA rating is terminated.

Pending the outcome of any subsequently required investigation, additional requirements on the Contractor shall include, but are not limited to, the following: restrictions on access to data by Contractor employees, subcontractor employees, and consultants; special storage requirements; restrictions on transmission and disclosure of information; changes in periods of retention and in methods of destruction of source documents or related material; and disclosure statements for all Contractor employees, subcontractor employees, and consultants.

The FDA Physical Security Staff may review the Contractor's facility and assess the Contractor's compliance. Recommendations for bringing noncompliant areas into compliance shall be provided to the Contractor by the FDA Physical Security Office.

The Contractor shall make any changes necessary within thirty (30) days after written notice from the FDA Physical Security Office in order to comply with FDA security requirements. When appropriate changes have been made, the Contractor shall contact the FDA Physical Security Office to request further review by the FDA. The FDA Physical Security Office will notify the Contractor in writing of the outcome of the second inspection. Failure of the Contractor to satisfy FDA security requirements within

thirty (30) days after the first written notification from the Contracting Officer may be cause for termination of the Contract.

The Contractor shall designate a Security Representative (could be a function assigned to the Program Coordinator) to act as liaison between the Contractor and the FDA on all security- related matters. This includes personnel changes, personnel terminations, disciplinary actions, etc.

H.3 COMMISSIONING OF INSPECTORS

The Government requires that certain Contractor personnel be commissioned by the Government to enable the Contractor to conduct activities under this Contract including, but not limited to, undertaking examinations, inspections, and investigations, and related activities to protect the public health in accordance with federal law, such as the provisions of "Public Health Security and Bioterrorism Preparedness and Response Act of 2002" (Public Law 107-188).

The Government has an established procedure to commission the Contractor's employees to perform certain functions pursuant to the FD&C Act such as conducting FDA examinations, inspections, and investigations, collecting and obtaining samples, copying and verifying records, and receiving and reviewing official FDA documents.

H.4 FEDERALLY FUNDED RESEARCH AND DEVELOPMENT CENTERS AND SUPPORT CONTRACTORS

The Government may contract with federally Funded Research and Development Centers (FFRDC) and support contractors for services to support in technical and management oversight of the Contractor's efforts and products under this Contract. Employees of these FFRDCs and support contractors may attend meetings between the Contractor and the Government, may observe and participate with Government personnel in function and performance tests, may review any and all documentation and underlying data supporting work performed under this Contract, and may have access to the Contractor's facilities as related to any effort under this Contract. No employee of an FFRDC or support contractor has the authority to issue directions to the Contractor or effect changes to the Contract.

The Contracting Officer will identify to the Contractor the FFRDCs and support contractors who will be supporting this Contract. The Contractor shall be provided the names of the FFRDC and support contractor personnel who will sign appropriate non-disclosure and conflict of interest statements. The Contractor agrees to cooperate with the FFRDCs and support contractors by engaging in technical discussions with their personnel, and permitting access to information and data relating to technical, cost, and schedule matters concerning this Contract to the same degree such access is accorded to Government personnel.

H.5 FDA PERSONNEL SECURITY CLEARANCE REQUIREMENTS

1. BACKGROUND

The Office of the Assistant Secretary for Management and Budget, Department of Health and Human Services (DHHS), requires that DHHS employees and contractor employees (including subcontractors) who will be working in a DHHS-owned or leased space and/or who will have access to DHHS equipment, and non-public privileged, proprietary, or trade secret information, undergo a background investigation of some type.

Contractor employees who will be in DHHS-owned or lease space for less than thirty (30) days are exempted from the background investigation requirement. These contractor employees must be escorted at all time while in DHHS-owned or leased space.

2. GENERAL

The contractor shall submit the following items to the Contracting Officer, ten (10) calendar days prior to commencement of work under this contract:

Certification that all required security form packets and a list of contractor employees names for whom the requisite security information has been provided to Division of Security Operations, Policy and Planning, Personnel Security Staff.

b. "Contractor's Commitment to Protect Non-public Information Agreement" forms signed by

each employee named in paragraph a. above.

With the exception of costs associated with fingerprinting Contractor employees outside of the FDA Personnel Security Office, the Government will conduct all required background investigations at no cost to the contractor. The cost of fingerprinting Contractor employees at any location other than the FDA Personnel Security Office will be borne by the Contractor.

Contractor employees shall obtain security badges in order to access to DHHS-owned or leased property without an escort. (See Section 3 for details on the badging process) However, in the event that work must commence before security badges can be issued, contractor employees will be allowed onto DHHS-owned or leased property, but must be escorted at all times.

All Contractor employees who undergo a background investigation are required to log onto the Office of Personnel Management's (OPM's) Electronic Questionnaire for Investigation Processing (e-QIP) system to complete the forms necessary to initiate their background investigations. The forms required vary with the position risk levels for the contract.

The position risk levels for this contract are Level 5.

There are two (2) potential position risk levels, which are:

Non-Sensitive Positions (Level 1) (SEE CHART A) - Positions which involve the lowest degree of adverse impact on the efficiency of the Agency. The forms set forth by CHART A are required for Non-Sensitive Positions (Level 1). Contractor employees assigned to Level 1 who receive a security badge will be required to provide additional security information for a background investigation as
specified in Paragraph 5 below.

b. Public Trust Positions (Levels 5 or 6) (SEE CHART B) - Positions in which the incumbent's actions or inaction could diminish public confidence in the integrity, efficiency, or effectiveness of assigned Government activities, whether or not actual damage occurs. The forms set forth by CHART B are required for Public Trust Positions (Levels 5 or 6). Contractor employees assigned Levels 5 or 6 must receive security badge as well as a background investigation.

In order to access the e-QIP system, Contractor employees must provide the appropriate Personnel Security Specialist with the following information: (a) full name; (b) position title; (c) social security number; (d) date of birth; (e) place of birth; (f) email address; and (g) phone number. The Personnel Security Specialist will use this information to initiate each Contractor employee into the e-QIP system. Once this is done, each Contractor employee will receive an email that contains a web link to access the e-QIP system, as well as instructions and additional forms needed to initiate the suitability background investigation. The Project Officer for the contract will provide the name of the appropriate Personnel Security Specialist to the

Contractor.

A Contractor's failure to comply with the e-QIP processing guidelines will result in that Contractor's employees being denied access to FDA property until all security processing has been completed.

3. BADGING PROCESS

The FDA Project Officer will sponsor Contractor employees on the FDA Form 3391 for the purpose of obtaining an FDA Security Access Card. In order to obtain one, a contractor employee must receive a "favorable" fingerprint return. Fingerprints must be submitted to the Personnel Security Office at least ten (10) days prior to the commencement of work. Fingerprints will be submitted in one of two ways, depending on where the contract will be performed:

Contractor employees who will work in the Washington D.C. metro area will, at the direction of the FDA Project Officer or his/her designee, contact the Personnel Security Branch to schedule a fingerprinting appointment, or Contractor employees who will work in a field office will submit fingerprints to:

Food and Drug Administration
Fingerprinting and Personnel Security Office
10903 New Hampshire Avenue, Building 1, Room 1201
Silver Spring, MD 20993

Upon the receipt of a "favorable" fingerprint return, each Contractor employee must present two forms of identification in order to receive his or her badge. One form of identification must be a government-issued photo identification document. Acceptable forms of photo identification are referenced on the FDA Form 3391. Acceptable forms of secondary identification are listed on the back of the I-9 Form. This form can be obtained at http://uscis.gov/graphics/formsfee/forms/files/i-9.pdf

An individual who receives an unfavorable report may appeal that finding by submitting a written request to the Personnel Security Staff.

4. BACKGROUND INVESTIGATIONS

The Government shall conduct an additional background investigation for those individuals named to risk Levels 1, 5 and 6 serving under this contract.

Required background investigations may include, but not be limited to: Review of

prior Government/military personnel records;

Review of FBI records and fingerprint files; Searches of

credit bureaus;

Personal interviews; and

Written inquiries covering the subject's background.

Background investigations will be conducted by the Office of Personnel Management (OPM). The Contractor is responsible for ensuring that the integrity of contract performance is maintained pending completion of all appropriate background investigations of contractor employees.

The Contractor shall submit the information required for eQIP access and other requisite forms for the risk level(s) specified. In addition, the contractor shall provide a cover letter which includes: the Contractor's name, the contract number, the name of the Contracting Officer administering the contract, the names of all Contractor employees' for whom a background check is required and those employees' social security numbers, dates of birth, and former names. This cover letter and all completed forms shall be transmitted, in a separate sealed envelope marked, "TO BE OPENED BY ADDRESSEE ONLY," to:

Food and Drug Administration
Badging and Credentialing Office
10903 New Hampshire Avenue, Building 1, Room 1201
Silver Spring, MD 20993

The contractor shall send a separate letter to the Contracting Officer that includes the contract number and employee names.

The contractor shall advise its prospective employees that all standard forms submitted to the FDA will be forwarded to the Office of Personnel Management (OPM) for scheduling background investigations.

Personnel Security Staff will resolve with the contract employee any issues arising out of inaccurate or incomplete forms.

Employees who have been previously granted a Government security clearance shall advise Personnel Security Staff of the details of such clearances to determine if a previous clearance level is suitable for the current FDA position.

At any time, if a contractor employee for whom security forms have been submitted is terminated or otherwise ceases work under the contract, the contractor shall immediately notify Personnel Security Staff, in writing, with copies to the respective FDA Project and Contracting Officers.

The OPM background investigation will take approximately 120 days. The Contracting Officer will notify the Contractor in writing if an employee is denied a clearance. Those individuals who have been cleared by Personnel Security Staff may continue to work under the contract. Those who are not cleared must cease work on the contract immediately.

If a Contractor employee changes job responsibilities under this contract, the contractor shall notify the Contracting Officer, and the Government will make a determination whether an additional security clearance is required.

In the event that a cleared individual is replaced, the contractor shall notify the Contracting Officer and comply with all requirements of this clause, as specified herein, prior to the commencement of work by the replacement individual.

The Contractor shall be responsible for the return of any Government issued security badges to the Project Officer.

5. NON-PUBLIC DATA PROTECTION

The contractor shall protect the privacy of all information reported by or about contract employees and shall protect against unauthorized disclosure.

CHARTS A & B ARE APPENDED TO THIS CLAUSE

For clarification purposes and to facilitate the flow of all required security forms, the following

matrix is provided:

CHART A

Mandatory for all on-site contract employees

NON-SENSITIVE POSITIONS - LEVEL 1				
FORM NAME	**OBTAIN FROM**	**WHEN REQUIRED**	**SUBMIT TO**	**DATE REQUIRED**
FDA Form 3391 - FDA Security Card Access Request	Project Officer. Sponsorship must be provided by FDA Project Officer.	All positions on DHHS property or leased space	Food and Drug Administration Attn: Badging and Credentialing Office 10903 New Hampshire Avenue Building 1, Room 1201 Silver Spring, MD 20993 **Form must be submitted by Security Rep.	Form must be received prior to making fingerprint appointment.
Contractor's Commitment to Protect Non-Public Information (NPI) Agreement form	Contracting Officer	All positions with access to non-public privileged, proprietary, or trade secret information	Contracting Officer for retention in contract file	Ten (10) calendar days prior to commencement of work
Listing of all contractor employee names, social security #s, gender, dates of birth, former names, and a completed Fair Credit Reporting Act Release	Contractor generated	All positions, including intermittent, per diem or temporary	*Food and Drug Administration Attn: Badging and Credentialing Office 10903 New Hampshire Avenue Building 1, Room 1201 Silver Spring, MD 20993 (301) 796-4592	Ten (10) calendar days prior to commencement of work

SF 85 - Questionnaire for Non-Sensitive Positions	Online via OPM's e-QIP system	Non-Sensitive Positions - Level 1 Clearance	*Submit to OPM online via the e-QIP system	Ten (10) calendar days upon request of the Contracting Officer
FD 258 - Fingerprint Chart (2 Charts Required) Fingerprinting services available by appointment only. Call (301) 827-9527	Contracting Officer	Non-Sensitive Positions - Level 1 Clearance	*Food and Drug Administration Fingerprinting & Personnel Security Office 10903 New Hampshire Avenue Building 1, Room 1201 Silver Spring, MD 20993 (301) 796-4607	Ten (10) calendar days prior to commencement of work

*In addition to the submission of these forms, the contractor shall provide a cover letter that includes: contractor's name, contract number, contractor employees' names, and name of Contracting Officer.

***Upon favorable fingerprint return, contractor will be notified to respond to the badging office for their building pass.**

CHART B

*Food and Drug Administration
Badging and Credentialing Office
8:00 a.m. – 11:00 a.m. and 1:00 p.m. – 3:00 p.m.
10903 New Hampshire Avenue
Building 1, Room 1201
Silver Spring, MD 20993
No appointment necessary
(301) 796-4592

Public Trust Positions - Levels 5 or 6				
FORM NAME	**OBTAIN FROM**	**WHEN REQUIRED**	**SUBMIT TO**	**DATE REQUIRED**
SF 85P - Questionnaire for Public Trust Positions	Online via OPM's e-QIP system	Public Trust Positions - Level 5 or 6 Clearance	*Submit to OPM online via the e-QIP system	Ten (10) calendar days prior to commencement of work
FD 258 - Fingerprint Chart (2 Charts Required) Fingerprinting services available by appointment only. Call (301) 827-9527	Contracting Officer	Public Trust Positions - Level 5 or 6 Clearance	*Food and Drug Administration Fingerprinting & Personnel Security Office 10903 New Hampshire Avenue Building 1, Room 1201 Silver Spring, MD 20993 (301) 796-4607	Ten (10) calendar days prior to commencement of work
FDA Form 3391 - FDA Security Card Access Request	Project Officer. Sponsorship must be provided by FDA Project Officer.	All positions on DHHS property or leased space	Food and Drug Administration Attn: Badging and Credentialing Office 10903 New Hampshire Avenue Building 1, Room 1201 Silver Spring, MD 20993 **Form must be submitted by Security Rep.	Form must be received prior to making fingerprinting appointment.
Contractor's Commitment to Protect Non-Public Information (NPI) Agreement form	Contracting Officer	All positions with access to non-public privileged, proprietary, or trade secret information	Contracting Officer for retention in contract file	Ten (10) calendar days prior to commencement of work
Listing of all contractor employee names, social security #s, gender, dates of birth, former names, and a completed Fair Credit Reporting Act Release	Contractor generated	All positions, including intermittent, per diem or temporary	*Food and Drug Administration Attn: Badging and Credentialing Office 10903 New Hampshire Avenue Building 1, Room 1201 Silver Spring, MD 20993	Ten (10) calendar days prior to commencement of work

			(301) 796-4592	

*

Upon favorable fingerprint return, contractor will be notified to respond to the badging office for their building pass.

*Food and DrugAdministration
Badging and Credentialing Office
8:00 a.m. – 11:00 a.m. and 1:00 p.m. – 3:00 p.m.
10903 New Hampshire Avenue
Building 1, Room 1201
Silver Spring, MD 20993
No appointment necessary
(301) 796-4592

*In addition to the submission of these forms, the contractor shall provide a cover letter that includes: contractor's name, contract number, contractor employees' names, and name of Contracting Officer.

SECTION I - CONTRACT CLAUSES

I.1 FAR 52.252-2 CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This Contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at these addresses: FAR – http://www.acquisition.gov/far
HHSAR – http://www.hhs.gov/oamp/policies/hhsar.doc

A. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

Reg	Clause	Date	Clause Title
FAR	52.202-1	Nov 2013	Definitions
FAR	52.203-3	Apr 1984	Gratuities
FAR	52.203-5	May 2014	Covenant Against Contingent Fees
FAR	52.203-6	Sept 2006	Restrictions on Subcontractor Sales to the Government
FAR	52.203-7	May 2014	Anti-Kickback Procedures
FAR	52.203-8	May 2014	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity
FAR	52.203-10	May 2014	Price or Fee Adjustment for Illegal or Improper Activity
FAR	52.203-12	Oct 2010	Limitation on Payments to Influence Certain Federal Transactions
FAR	52.203-13	Oct 2015	Contractor Code of Business Ethics and Conduct
FAR	52.203-16	Dec 2011	Preventing Personal Conflicts of Interest
FAR	52.203-17	Apr 2014	Contractor Employee Whistleblower Rights and Requirement to Inform Employees of Whistleblower Rights
FAR	52.204-4	May 2011	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper
FAR	52.204-7	Jul 2013	System for Award Management
FAR	52.203-19	Jan 2017	Prohibition on Requiring Certain Internal Confidentiality
FAR	52.204-9	Jan 2011	Personal Identity Verification of Contractor Personnel
FAR	52.204-10	Oct 2015	Reporting Executive Compensation and First-Tier Subcontract Awards
FAR	52.204-13	Jul 2013	System for Award Management Maintenance
FAR	52.204-14	Jan 2014	Service Contract Reporting Requirements
FAR	52.209-6	Oct 2015	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment
FAR	52.209-9	Jul 2013	Updates of Publically Available Information Regarding Responsibility Matters
FAR	52.209-10	Nov 2015	Prohibition on Contracting With Inverted Domestic
FAR	52.215-2	Apr 1998	Audit and Records – Negotiation (ALT II)
FAR	52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
FAR	52.215-10	Aug 2011	Price Reduction for Defective Certified Cost or Pricing Data
FAR	52.215-12	Oct 2010	Subcontractor Certified Cost or Pricing Data
FAR	52.215-15	Oct 2010	Pension Adjustments and Asset Reversions

FAR	52.215-18	Jul 2005	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
FAR	52.215-19	Oct 1997	Notification of Ownership Changes
FAR	52.215-20	Oct 2010	Requirements for Certified Cost or Pricing Data and Data
FAR	52.232-1	Apr 1984	Payments
FAR	52.215-23	Oct 2009	Limitations of Pass-Through Charges (Alternate I)
FAR	52.216-7	Jun 2013	Allowable Cost and Payment (Alternate III)
FAR	52.216-11	Apr 1984	Cost Contract-No Fee
FAR	52.222-3	Jun 2003	Convict Labor
FAR	52.222-17	May 2014	Non-displacement of Qualified Workers
FAR	52.222-26	Apr 2015	Equal Opportunity
FAR	52.222-35	Oct 2015	Equal Opportunity for Veterans
FAR	52.222-36	Jul 2014	Affirmative Action for Workers with Disabilities
FAR	52.222-37	Oct 2015	Employment Reports on Veterans
FAR	52.222-50	Mar 2015	Combating Trafficking in Persons
FAR	52.222-54	Oct 2015	Employment Eligibility Verification
FAR	52.223-6	May 2001	Drug-Free Workplace
FAR	52.223-18	Aug 2011	Encouraging Contractor Policies to Ban Text Messaging While Driving
FAR	52.224-1	Apr 1984	Privacy Act Notification
FAR	52.224-2	Apr 1984	Privacy Act
FAR	52.225-1	Feb 2009	Buy American Act - Supplies
FAR	52.225-13	June 2008	Restrictions on Certain Foreign Purchases
FAR	52.227-1	Dec 2007	Authorization and Consent
FAR	52.227-17	Dec 2007	Rights in Data – Special Works
FAR	52.232-20	Apr 1984	Limitation of Cost
FAR	52.232-23	May 2014	Assignment of Claims
FAR	52.232-25	Jul 2013	Prompt Payment
FAR	52.232-40	Dec 2013	Providing Accelerated Payments to Small Business Subcontractors (Dec 2013)
FAR	52.232-33	Jul 2013	Payment by Electronic Funds Transfer-System for Award Management
FAR	52.232-39	Jun 2013	Unenforceability of Unauthorized Obligations
FAR	52.233-1	May 2014	Disputes
FAR	52.233-3	Aug 1996	Protest After Award (ALT I)
FAR	52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
FAR	52.242-13	Jul 1995	Bankruptcy
FAR	52.243-2	Aug 1987	Changes – Cost Reimbursement (ALT II)
FAR	52.244-2	Jun 2007	Subcontracts (ALT I)
FAR	52.245-1	Apr 2012	Government Property
FAR	52.245-9	Apr 2013	Use and Charges
FAR	52.246-5	Apr 1984	Inspection of Services
FAR	52.249-6	May 2004	Termination (Cost Reimbursement) (ALT II)
FAR	52.249-14	Apr 1984	Excusable Delays
FAR	52.253-1	Jan 1991	Computer Generated Forms

B. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CONTRACT

CLAUSES

Reg	Clause	Date	Clause Title
HHSAR	352.203-70	Dec-15	Anti-Lobbying
HHSAR	352.222.70	Dec-15	Contractor Cooperation in Equal Employment
HHSAR	352.224-70	Dec-15	Privacy Act
HHSAR	352.224-71	Dec-15	Confidential Information
HHSAR	352.231-70	Dec-15	Salary Rate Limitation
HHSAR	352.233-71	Dec-15	Litigation and Claims

I.2 FAR CLAUSES IN FULL TEXT

FAR 52.217-8 OPTION TO EXTEND SERVICES (NOV 1999)

The Government may require continued performance of any services within the limits and at the rates specified in the Contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed six (6) months. The Contracting Officer may exercise the option by written notice to the Contractor prior to the expiration of the contract.

FAR 52.217-9 OPTION TO EXTEND THE TERM OF THE CONTRACT (MAR 2000)

(a) The Government may extend the term of this contract by written notice to the Contractor prior to expiration of the Contract; provided that the Government gives the Contractor a preliminary written notice of its intent to extend before the contract expires. The preliminary notice does not commit the Government to an extension.

(b) If the Government exercises this option, the extended contract shall be considered to include this option clause.

(c) The total duration of this contract, including the exercise of any option under this clause, shall not exceed three (3) years.

SECTION J - LIST OF ATTACHMENTS

The following are attachments for this solicitation.

Attachment 1: List of Materials

Attachment 2: Retail Outlet List Template and Instructions

Attachment 3: Monthly Report Template

Attachment 4: Form FDA 3398 – Commitment to Protect Non-Public Information (NPI) Agreement

Attachment 5: Cost Estimate Formatting Example

Attachment 6: SF LLL Disclosure of Lobbying Activities

SECTION K - REPRESENTATIONS,

CERTIFICATIONS AND OTHER

STATEMENTS OF OFFERORS

K.1 52.204-8 ANNUAL REPRESENTATIONS AND CERTIFICATIONS (Dec 2014)

To Be Completed by the Offeror: This document must be completed and included as part of your Business Proposal. By submission of its signed offer, the offeror makes the following Representations and Certifications:

(a)

(1) The North American Industry classification System (NAICS) code for this acquisition is _____ [insert NAICS code].

(2) The small business size standard is _____ [insert size standard].

(3) The small business size standard for a concern which submits an offer in its own name, other than on a construction or service contract, but which proposes to furnish a product which it did not itself manufacture, is 500 employees.

(b)

(1) If the provision at 52.204-7, System for Award Management, is included in this solicitation, paragraph (d) of this provision applies.

(2) If the provision at 52.204-7 is not included in this solicitation, and the offeror is currently registered in the System for Award Management (SAM), and has completed the Representations and Certifications section of SAM electronically, the offeror may choose to use paragraph (d) of this provision instead of completing the corresponding individual representations and certification in the solicitation. The offeror shall indicate which option applies by checking one of the following boxes:

[_] (i) Paragraph (d) applies.

[_] (ii) Paragraph (d) does not apply and the offeror has completed the individual representations and certifications in the solicitation.

(c)

(1) The following representations or certifications in SAM are applicable to this solicitation as indicated:

(i) 52.203-2, Certificate of Independent Price Determination. This provision applies to solicitations when a firm-fixed-price contract or fixed-price contract with economic price adjustment is

contemplated, unless—

(A) The acquisition is to be made under the simplified acquisition procedures in Part 13;

(B) The solicitation is a request for technical proposals under two-step sealed bidding procedures; or

(C) The solicitation is for utility services for which rates are set by law or regulation.

(ii) 52.203-11, Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions. This provision applies to solicitations expected to exceed $150,000.

(iii) 52.204-3, Taxpayer Identification. This provision applies to solicitations that do not include the provision at 52.204-7, System for Award Management.

(iv) 52.204-5, Women-Owned Business (Other Than Small Business). This provision applies to solicitations that—

(A) Are not set aside for small business concerns;

(B) Exceed the simplified acquisition threshold; and

(C) Are for contracts that will be performed in the United States or its outlying areas.

(v) 52.209-2, Prohibition on Contracting with Inverted Domestic Corporations—Representation.

(vi) 52.209-5; Certification Regarding Responsibility Matters. This provision applies to solicitations where the contract value is expected to exceed the simplified acquisition threshold.

(vii) 52.214-14, Place of Performance--Sealed Bidding. This provision applies to invitations for bids except those in which the place of performance is specified by the Government.

(viii) 52.215-6, Place of Performance. This provision applies to solicitations unless the place of performance is specified by the Government.

(ix) 52.219-1, Small Business Program Representations (Basic & Alternate I). This provision applies to solicitations when the contract will be performed in the United States or its outlying areas.

(A) The basic provision applies when the solicitations are issued by other than DoD, NASA, and the Coast Guard.

(B) The provision with its Alternate I applies to solicitations issued by DoD, NASA, or the Coast Guard.

(x) 52.219-2, Equal Low Bids. This provision applies to solicitations when contracting by sealed bidding and the contract will be performed in the United States or its outlying areas.

(xi) 52.222-22, Previous Contracts and Compliance Reports. This provision applies to solicitations that include the clause at 52.222-26, Equal Opportunity.

(xii) 52.222-25, Affirmative Action Compliance. This provision applies to solicitations, other than those for construction, when the solicitation includes the clause at 52.222-26, Equal Opportunity.

(xiii) 52.222-38, Compliance with Veterans' Employment Reporting Requirements. This provision applies to solicitations when it is anticipated the contract award will exceed the simplified acquisition threshold and the contract is not for acquisition of commercial items.

(xiv) 52.223-1, Biobased Product Certification. This provision applies to solicitations that require the delivery or specify the use of USDA-designated items; or include the clause at 52.223-2, Affirmative Procurement of Biobased Products Under Service and Construction Contracts.

(xv) 52.223-4, Recovered Material Certification. This provision applies to solicitations that are for, or specify the use of, EPA- designated items.

(xvi) 52.225-2, Buy American Certificate. This provision applies to solicitations containing the clause at 52.225-1.

(xvii) 52.225-4, Buy American--Free Trade Agreements--Israeli Trade Act Certificate. (Basic, Alternates I, II, and III.) This provision applies to solicitations containing the clause at 52.225- 3.

(A) If the acquisition value is less than $25,000, the basic provision applies.

(B) If the acquisition value is $25,000 or more but is less than $50,000, the provision with its Alternate I applies.

(C) If the acquisition value is $50,000 or more but is less than $79,507, the provision with its Alternate II applies.

(D) If the acquisition value is $79,507 or more but is less than $100,000, the provision with its Alternate III applies.

(xviii) 52.225-6, Trade Agreements Certificate. This provision applies to solicitations containing the clause at 52.225-5.

(xix) 52.225-20, Prohibition on Conducting Restricted Business Operations in Sudan--Certification. This provision applies to all solicitations.

(xx) 52.225-25, Prohibition on Contracting with Entities Engaging in Certain Activities or Transactions Relating to Iran—Representation and Certification. This provision applies to all solicitations.

(xxi) 52.226-2, Historically Black College or University and Minority Institution Representation. This provision applies to solicitations for research, studies, supplies, or services of the type normally acquired from higher educational institutions.

(2) The following certifications are applicable as indicated by the Contracting Officer:

[Contracting Officer check as appropriate.]

___ (i) 52.204-17, Ownership or Control of Offeror.

___ (ii) 52.222-18, Certification Regarding Knowledge of Child Labor for Listed End Products.

___ (iii) 52.222-48, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment--Certification.

___ (iv) 52.222-52 Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services--Certification.

___ (v) 52.223-9, with its Alternate I, Estimate of Percentage of Recovered Material Content for EPA-Designated Products (Alternate I only).

___ (vi) 52.227-6, Royalty Information.

___ (A) Basic.

___ (B) Alternate I.

___ (vii) 52.227-15, Representation of Limited Rights Data and Restricted Computer Software.

(d) The offeror has completed the annual representations and certifications electronically via the SAM Web site accessed through https://www.acquisition.gov . After reviewing the SAM database information, the offeror verifies by submission of the offer that the representations and certifications currently posted electronically that apply to this solicitation as indicated in paragraph (c) of this provision have been entered or updated within the last 12 months, are current, accurate, complete, and applicable to this solicitation (including the business size standard applicable to the NAICS code referenced for this solicitation), as of the date of this offer and are incorporated in this offer by reference (see FAR 4.1201); except for the changes identified below [offeror to insert changes, identifying change by clause number, title, date]. These amended representation(s) and/or certification(s) are also incorporated in this offer and are current, accurate, and complete as of the date of this offer.

FAR Clause
Title
Date
Change

Any changes provided by the offeror are applicable to this solicitation only, and do not result in an update to the representations and certifications posted on SAM.

(End of Provision)

SECTION L – INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

L.1 FAR 52.252-1 SOLICITATION PROVISIONS INCORPORATED BY REFERENCE (JUN 1988)

This solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at these addresses:

FAR –
http://www.acquisition.gov/far
HHSAR –
http://www.hhs.gov/oamp/policies/hssar.doc

FAR Clause No.	Date	Title
52.203-18	Jan 2017	Prohibition on Contracting with Entities that Require…
52.215-2	Oct 2010	Audit and Records – Negotiation (ALT II)
52.215-22	Oct 2009	Limitations on Pass-Through Charges (ALT)

HHSAR Clause No.	Date	Title
352.239-73	Jan 2006	Electronic and Information Technology Accessibility

FAR 52.216-1 TYPE OF CONTRACT (APR 1984)

The Government contemplates award of a Cost-Reimbursement type contract resulting from this solicitation.

L.2 GENERAL INFORMATION

A. COMMUNICATIONS PRIOR TO CONTRACT AWARD

Offeror shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with other officials may compromise this acquisition and result in cancellation of the requirement.

A. RELEASE OF INFORMATION

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition.

C. PREPARATION COSTS

This Request for Proposal does not commit the Government to pay any cost for the preparation and submission of a proposal. In addition, the Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed acquisition.

D. FAR 52.233-2 SERVICE OF PROTEST (SEPT 2006)

Protests, as defined in Section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accountability
Office (GAO), shall be served on the Contracting Officer (addressed as following) by obtaining written and dated acknowledgment of receipt from:

Contracting Officer
Food and Drug Administration
Office of Acquisitions and Grants Services\
5630 Fishers Lane
Rockville, Maryland 20857
Attn: [name to be inserted]

The copy of any protests shall be received in the office designated above within one day of filing a protest with the GAO.

L.3 PROPOSAL INSTRUCTIONS

The Proposal **must** be prepared and submitted in three parts: **Volume I - Technical Proposal**, **Volume II - Business Proposal**, and **Volume III – Past Performance**. Each of the volumes shall be separate and complete so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other.

However, the Technical Proposal shall **not** include pricing data related to indirect cost rates or amounts, fee amounts (if any), and total costs. The Technical Proposal shall disclose your technical approach in as much details as possible, including, but not limited to, the requirements of the Technical Proposal instructions. The technical proposal (Volume I) shall be limited to 50 pages with a 12 point font. This limitation excludes resumes, commitment documentation, and supporting documentation. The technical proposal shall include a table of contents for each section described below.

L.4 VOLUME I - TECHNICAL PROPOSAL INSTRUCTIONS

The Offeror's transmittal and cover letter for the proposal must contain the name, phone number, and e-mail address of the person to be contacted concerning any matter related to the proposal submitted.

The Technical Proposal is the most important item in the evaluation of your capability to perform the desired services. Therefore, your proposal must present sufficient information to reflect a thorough understanding of the work requirements and a detailed technical approach for achieving project objectives as set forth in Section C.

To permit a thorough and effective evaluation, the technical volume of your proposal must be as concise, complete and clear as possible to enable the Government to make a sound determination of your ability to successfully complete the requirements set forth in the SOW. The inclusion of any important considerations not covered by this request is encouraged. Statements to the effect that the Offeror "understands and will comply" with the SOW (in whole or in part) or phrases such as "standard procedures will be used" or "well-known techniques will be utilized" and other such generalities will not constitute compliance with the requirements. It is essential that you present in your proposal, information in sufficient detail to permit the Government to make an evaluation of the technical proposal without further information being required. The

Government reserves the right to award without conducting discussions. Offerors shall clearly state any areas in which assumptions are based or clearly state areas that deviate from the requirements stated in Section C. The following areas shall be addressed:

A. TECHNICAL APPROACH INCLUDING PHYSICAL SECURITY PLAN

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan in relation to the work described in Section C. Demonstrate understanding of Tobacco Control Act, the commissioning process and inclusion of personnel, or subcontractors, who are able to be commissioned as inspectors and undercover buy and advertising and labeling enforcement inspections. In order to be commissionable, the inspector must be a health, food, or drug officer/employee of any State, Territory, or political subdivision thereof. Note: This definition of commissionable applies throughout.

The Contractor shall describe in their proposal their procedures and standards to ensure the anonymity of inspection participants, the confidentiality of data and evidence throughout its collection, transmission, and storage, and chain of custody of evidence. The procedures and standards outlined in the proposal should also include the handling, use, and protection of FDA property and physical evidence. *See* Section H.2.

B. CORPORATE EXPERIENCE

The Offeror shall provide information for 3 projects that are similar to this effort in terms of type, scope, complexity and size. The Offeror shall describe their current and past experience, identifying other organizations for which they have performed similar tasks including the degree of their involvement (prime or subcontractor), the size of the client's organization, and other information to describe their expertise and performance in the subject areas, highlighting the organization's demonstrated successes. Projects listed may include those entered into by the Federal Government, agencies of state and local governments, and commercial customers.

For each project identified above, the Offeror shall submit the following information:

- Name of contracting activity (Federal Government agency, local government, commercial customer);
- Contract number;
- Contract type;
- Total contract value, and subcontract value (if applicable);
- Contracting Officer contact information (phone, fax, email);
- Project Officer/Contracting Officer's Technical Representative contact information (phone, fax, email);
- Administrative Contracting Officer contact information – if different from item 5 (phone, fax, email);
- Description of work; and
- Narrative highlighting the relevance of the work performed in terms of type, scope, complexity, and size.

C. ORGANIZATION AND STAFFING PLAN INCLUDING KEY PERSONNEL AND PLAN FOR RECRUITING, TRAINING, AND MAINTAINING THE SAFETY OF THE MINORS

Information shall be provided which will demonstrate your understanding and management of important events or tasks. Provide the following information as it relates to the Contractor and Subcontractor.

- Provide the organizational structure of the personnel (e.g., technical supervisors, administrative staff, Inspectors, adult supervisors/chaperones, as applicable) and the number of hours proposed for each position; describe how the personnel are or will be employed, organized, and physically located (e.g., regionally or centrally located); and for each proposed employee, describe whether they currently employed by the Offeror, planning to join the organization, a subcontractor, or other arrangements have been made.

- Specify the commissionable contractor employees/subcontractors that will be utilized to perform inspection work on this contract. For the commissionable employees and/or subcontractors that will be performing inspections, describe each inspector's qualifications as a health, food or drug officer/employee of any State, Territory, or political subdivision thereof and include documentation (i.e. paystubs or official letter) verifying such from each inspector's respective employer.

- Provide a brief description of the qualifications and experience of the proposed key personnel, the Program Coordinator and Backup Program Coordinator. Resumes shall be included for all proposed key personnel.

D. PROGRAM MANAGEMENT

Detail how the program management will affect the compliance check inspection by including the following:

- Description of the make-up of your proposed tobacco inspection teams (e.g., 2 Inspectors with 1 Minor for undercover buy assignments, and 1 Inspector for advertising and labeling assignments).
- A proposed tobacco inspection plan that includes how the offeror plans to conduct the undercover buy and advertising and labeling assignments. Emphasize if any procedure seems to vary from FDA's protocol described in section C.1, Scope of Work.
- Estimated or current violation rate.
- Discussion of issues/challenges and your plan to address these issues.
- Describe the approach to recruit, hire, insure, and train Minors.
- Describe the plan for coverage of program management duties at times when the Program Coordinator is unavailable.

E. SCHEDULE

To assist the FDA in working with each Contractor to implement their program, provide a draft schedule for completion of the work and action outcomes in the table below.

Description	Timeline
Provide security contact information	
Hiring Program Coordinator and Backup Program Coordinator	
Recruiting/Hiring Commissioned Officers	
Submission to FDA list of individuals to be commissioned (takes approximately 8 weeks to issue commissions upon receipt of documentation)	
Recruiting/hiring of Minors	
Training of Program Coordinator and Backup Program Coordinator	
Compilation of all required documents for Minors	
Training of Minors	
Submission to FDA of all required Minor information	
Submission to FDA of the Quality Control Plan	
Training of Commissioned Officers	
Begin inspections	

F. INSPECTION PLAN FOR RETAILERS

In order to accurately understand and evaluate retail inspections being proposed, please provide the following:

- A detailed plan for ensuring that contractor directed inspections are conducted at a variety of different types of locations (urban, suburban, rural, and racial and ethnic minority communities) and outlet types throughout its jurisdiction shall be included in the technical proposal. A discussion of the plan to provide inspectional coverage throughout the state/territory shall also be provided.
- A plan to cover retail outlets in racial and ethnic minority communities as required in the Tobacco Control Act.
- An estimated number of inspections per month.
- If the Offeror anticipates difficulty providing the required inspectional coverage as outlined in Section C due to geographical and logistical considerations, the Technical Proposal must address these issues.

G. LIST OF RETAIL OUTLETS

The Contractor shall describe their plan to create an up-to-date list of all current retail outlets within its jurisdiction that sell tobacco products, if available. The plan shall detail the state specific sources; methods of obtaining sources; or other details to obtain or create the tobacco

retailer list. If Government sources are to be used, the plan shall include the methods by which the information will be obtained and a reasonable projected timeline for doing so.

The retail outlet list must include the retail outlet name (the outlets trade name or Doing Business As name is required and its legal name is optional), physical address, mailing address (including zip codes), unique ID number, as well as the name and mailing address of the legal owner(s) of the retail outlet, if available. The retail outlet list should be submitted electronically as a spreadsheet compatible with Excel and should not contain duplicate records for any retail outlet. See Section J, Attachment 2 for the required format for the retail outlet list.

If current FDA Contractors have retail outlet information already uploaded into TIMS, this information will remain in TIMS. Current Contractors are not required to submit a new retail outlet list. However, Contractors will still need to follow all other requirements related to Section C, Retail Outlet List, such as providing updated retail outlet information as it becomes available and assisting FDA with researching ownership information.

H. QUALITY CONTROL PLAN

The Contractor shall submit a Quality Control Plan with its Technical Proposal, which must include, at a minimum, realistic and comprehensive measures to identify and document problems, determine corrective actions, and determine improvement based upon corrective actions. The plan shall also include the Offeror's procedures for ensuring accuracy of the tasks and provided in the final deliverables. Lastly, the plan shall describe the measures the Contractor has in place to protect FDA/CTP information in their possession and information that they have developed for CTP.

L.5 VOLUME II – BUSINESS PROPOSAL INSTRUCTIONS

The Business Proposal shall consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions set forth below. There is no page limitation for the business proposal.

Include the following information in your cover letter:

1. DUNS number and Taxpayer Identification Number;
2. Company Name mailing address, telephone number and website address;
3. Date submitted and proposal expiration date (shall remain valid through September 30, 2013);
4. All of the above-cited information for each entity on the proposed team, if a team is proposed or if a Subcontractor is proposed;
5. Do you have a Government approved accounting system? If so, please identify the agency that approved the system; and
6. SAM/DUNS/ORCA – NOTE: in order to receive a federal government contract, Contractors must register at www.sam.gov; www.dnb.com; and www.orca.bpn.gov. The cover letter shall acknowledge registration in these systems.

Authorized Official and Submission of Proposals: The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP.

A. COST OR PRICING DATA

Offerors must submit, as a minimum, cost proposals fully supported by cost and pricing data adequate to establish the reasonableness of all proposed costs.

This breakdown of costs must be shown for each year of the contract. Offerors shall also summarize total costs for the entire contract period by individual category. See items B-G below. A Cost Estimate Pricing Format has been included as Attachment 5. This format is provided to assist Offerors with providing the required information for each year of contract performance and to summarize costs for the entire contract period. (Base Period; Option Period I; Option Period II; and total Base and Option Periods).

Proposed hourly rates shall be supported by the submission of the employee's most recent payroll stub or leave and earnings statement. Documentation to verify salaries for new hires shall consist of written offers of employment, employment agreements or contracts, which indicate the position, annual salary, and hourly rate for each new hire.

The offeror's proposal should indicate whether escalated rates are used. If escalation is included, state the percent and methodology, e.g. annual flat rate applied to a base rate as of a specific date or a midpoint rate for the period of performance. Salary increases that are anticipated during contract performance must be claimed under the contract. Plans for any additional compensation resulting from employee relations, profit sharing, pensions or health and welfare benefits should also be included. The offeror shall also state whether overtime will be required under the contract and the overtime premium rate to be applied for all direct labor proposed.

The offeror shall indicate in its proposal whether or not it has the necessary financial capacity, working capital and other resources to perform without assistance from any outside sources. (If not, you must indicate the amount required and the anticipated source). Documentation to verify indirect cost rates such as the offeror's most recent indirect cost rate agreement with its cognizant audit agency shall be submitted as a part of the proposal. A copy of the offeror's most recent audited financial statements should also be included. Additional documentation such as vendor quotes, invoices and historical data must be submitted to support other direct costs proposed. Failure to include supporting documentation with proposal submission will delay the procurement process. This support is essential to determine the proposed Other Direct Costs (ODC's) are fair and reasonable.

B. DIRECT LABOR

Offerors must submit supporting schedules indicating types or categories of labor, together with person-hours. If you use anything other than actual hours, state the basis of the full-time equivalency, i.e., 2,000 hours, 2080 hours, etc.

State whether any additional direct labor (new hires) will be required during the performance period of this procurement. If so, state the number required and anticipated date of hire.

C. OVERHEAD, GENERAL AND ADMINISTRATIVE EXPENSE

Unless your proposed burden rate(s) has recently been accepted by an agency of the U.S. Government, detailed projected estimates of the various items which are included in the total overhead pools are required. These projected estimates shall be based upon past actuals as well as upon the planned mode and level of operation during the period in which effort is to be expended under the subject contract. These estimates shall take into consideration all operating changes. Details of cost incurred in the previous fiscal year and current year to date shall also be presented. If you have an approved indirect cost rate agreement, it must be included with proposal submission.

D. TRAVEL EXPENSE

Attach a schedule indicating the estimated number of person-trips required, destinations, mode and cost of transportation, and the number of days of subsistence per trip. Identify and support any other special transportation costs attributable to the performance of this project.

Offerors shall estimate travel costs for the annual in-person training in Washington, D.C. for two (2) full days for two (2) persons for each contract period of performance. For any proposed long distance travel, the offeror shall identify the number of trips, the destination, duration of each trip, the proposed air fare, per diem and any other travel expenses for each trip. All travel costs shall be proposed in accordance with the Federal Travel Regulations (FTR) at http://gsa.gov/portal/content/104790. Offerors shall include the breakdown of proposed costs and supporting documentation (i.e., air fare or travel quotes, per diem, etc). Please do not include an estimate of the lodging costs for attendees as CTP is planning on covering that cost.

E. CONSULTANT SERVICES

Consultant Services are separate from a subcontract. Consultant service shall be explained by indicating the specific area in which such service is to be used such as, former inspectors needed to provide testimony. Identify the contemplated consultants. State the number of days of such service estimated to be required and the consultant's quoted rate per day, and indicate the number of hours per day in which work will be performed. State whether the consultant has received the proposed rate in performing similar services for other contractors. Offerors shall include a copy of the consultant agreement with proposal submission.

F. OTHER DIRECT COSTS

Offerors shall propose Other Direct Costs (ODC's) that may be necessary to perform the requirements of the contract. (i.e., office supplies, postage, hardware, connectivity, software, maintenance, etc). Offerors must include supporting documentation to support each ODC proposed (competitive bids, catalog prices, quotes, receipts, etc). This support shall be used to facilitate analysis to determine the ODC's are fair and reasonable. Failure to submit supporting documentation will delay the acquisition process. In addition, a written explanation for each ODC proposed shall be provided. If the offeror proposes any training, the offeror shall identify the courses it is proposing to take, the cost of each course, the basis of the cost and the reason each course is needed.

G. EXAMPLE COST FORMAT

While the above cost elements are representative, they are not intended to be all-inclusive of the items which may be contained in your cost proposal. Offerors are expected to make an independent assessment of the resources required to perform the tasks described in the scope of work. This information shall be provided for each contract period of performance as well as a total for the base and option periods. A sample table that may be used to outline your estimated costs is included as an attachment. (See Section J, Attachment 5, Cost Estimate Formatting Example). Each cost included in the Offeror's cost estimate should be accompanied by a description of how the cost was calculated.

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H. ADDITIONAL DOCUMENTS TO BE SUBMITTED WITH BUSINESS PROPOSAL

1. Offerors must complete and include Standard Form 33, blocks 15a and b, 16, 17, and 18. If the Government issued any amendments, acknowledgement of the amendments shall be provided on Standard Form 33. Completion of this form indicates that the Offeror agrees with all the terms and conditions contained in RFP Sections B through K.
2. The Offeror must complete Section K of the RFP, Representations, Certifications, and other Statement of Offerors. One originally signed copy of Section K must be included with the original business proposal.
3. Disclosure and Use of Lobbying Activities - Standard Form LLL, "Disclosure of Lobbying Activities" has been included in the Section J, Attachment 6 for use in accordance with FAR 52.203-ll-Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions (APR l991) and is accessible at http://www.gsa.forms. If the Offeror has activity to report, it shall complete SF-LLL "Disclosure of Lobbying Activities" and shall include one originally signed copy with the business proposal.

L.6 VOLUME III – PAST PERFORMANCE INFORMATION

Offerors shall submit the following information as part of their Proposal (for both the Offeror and proposed major subcontractors):

A list of the last three (3) contracts completed during the last five (5) years and all contracts currently in process that are similar in nature to the solicitation work scope. Contracts listed may include those entered into with the federal Government, agencies of state and local government, and commercial customers. Offerors that are newly formed entities without prior contracts should list contracts and subcontracts as required above for all key personnel. Include the following information:

- Name of Contracting Organization
- Contract number
- Contract Type
- Total Contract Value
- Description of requirement
- Contracting Officer's name and telephone number
- Project Officer's name, email and telephone number

The Offeror shall be evaluated on its performance under existing and prior contracts for similar services. Performance information will be used for both responsibility determination and as an evaluation factor to assure the best value to the Government. The Government will focus on the information that demonstrates quality of performance relative to the size and complexity of the acquisition under consideration.

L.7 RFP INQUIRIES AND QUESTIONS DUE DATE

All questions regarding the solicitation, of a contractual nature or technical nature, must be submitted in writing and sent via email to Madeline.Bryant@fda.hhs.gov by **April 6, 2017 AT 2:00 P.M. EASTERN TIME.** The Government may not consider any questions received after this date and time. All questions received and any amendments to this solicitation will be answered and posted on Federal Business Opportunities (FBO) at www.fbo.gov.
Note: Only written amendments/notices posted on FBO by the FDA Contracting Office shall be deemed the Government's official response.

L.8 PRE-PROPOSAL CONFERENCE

A pre-proposal conference call will be held at two different times on **April 06, 2017**.
The first conference call will be held **April 06, 2017 at 6:00 am EST** and the second conference call will be held on **April 06, 2017 at 2:00 pm EST**. Interested parties must submit any questions and the information below via email to Madeline.Bryant@fda.hhs.gov by **12:00 P.M., EASTERN TIME, April 05, 2017** for inclusion in the pre-proposal conference call.

Interested parties must submit any questions and the information below via email to Madeline.Bryant@fda.hhs.gov @ **1:00 P.M., EASTERN TIME, April 05, 2017** for inclusion in the pre-proposal conference call.

Emails shall include the following for all participants:
Name
State Organization
Email Address

Information disseminated on the call will be posted on FBO by the FDA Contracting Office following the conference.

L.9 PROPOSAL SUBMISSION

Offerors who are interested in this RFP must submit their proposal by **May 04, 2017 NO LATER THAN 1:00 P.M., EASTERN TIME.** Offerors shall submit one (1) hard-copy original of Volumes I, II, and III to the address below. Offerors must also submit an electronic copy of Volumes I, II, and III via email to Madeline.Bryant@fda.hhs.gov.

HHS/FDA/Office of Acquisitions and Grants Services
5630 Fishers Lane, Room 2136, Mail Stop HFA-500
Rockville, MD 20857
Attn: Madeline Bryant 240-402-7611

SECTION M - EVALUATION FACTOR FOR AWARD

M.1 BASIS FOR AWARD

The Government will award a contract to the company that can satisfy the technical requirements contained in Section C, and that has submitted a proposal that represents the best value to the Government. When combined, all non-cost factors are considered significantly more important than cost. The Government reserves the right to award without conducting discussions; therefore, the Offeror's initial proposal shall be their best effort to perform the work described herein.

M.2 TECHNICAL AND PAST PERFORMANCE EVALUATION

Mandatory Requirement: In order for an offer to be deemed acceptable, the offer must satisfy the below listed mandatory requirement. Proposals not meeting the mandatory requirements will be excluded from further evaluation. The mandatory requirement is as follows:

The Contractor and any subcontracted entity, conducting compliance check inspections under this contract as Inspectors of FDA, shall have the authority to conduct or facilitate the conduct of the FDA tobacco compliance check inspections by meeting the requirements to be a "Contractor" as described in Section C or provide documentation demonstrating that such authority is conveyed to the entity conducting the compliance check inspections through appropriate means - e.g., state legislation. **To be considered for award, Offerors must clearly demonstrate their proposals to meet the requirements regarding commissionable inspectors and minimum retailer inspection percentages. Offerors that do not demonstrate they meet these requirements will be considered technically unacceptable.**

Technical Evaluation: For those offers that satisfy the above mandatory requirement, the offer will be further evaluated in accordance with the following evaluation factors (all equal of importance):

1. Technical approach, including physical security plan
2. Corporate Experience
3. Organization and Staffing, including Key Personnel, and plan for recruiting, training, and maintaining the safety of the Minors
4. Program Management
5. Schedule
6. Inspection Plan for Retailers, including proposed list of retail outlets
7. Quality Control Plan

Past Performance Evaluation: In order for any declared past performance to be considered, the work must be relevant which is qualified as being similar in size, scope and complexity to the requirements outlined in the SOW. Past performance evaluation will consider information/sources outside of the information received in response to the solicitation. Past performance will not be scored, but the Government's conclusions about overall quality of the offeror's past performance will be highly influential in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered the most advantageous/best value to the Government. The assessment of the offerors past performance will be used as a means of evaluating the relative capability of the offeror and the other competitors. Thus, an offeror with an exceptional record of relevant past performance may

receive a more favorable evaluation than another whose record is acceptable and/or less relevant, even though both may have acceptable technical and business proposals. An offeror without a record of past performance or for whom information on past performance is not available will not be evaluated favorably or unfavorably.

M.3 PRICE EVALUATION

The price of the base period and all option periods shall be added together in determining the total estimated cost of the proposal.

M.4 FAR 52.217-5 EVALUATION OF OPTIONS (JUL 1990)

Except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests, the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement. Evaluation of options will not obligate the Government to exercise the option(s).